Alternative Medicine and Ethics

BIOMEDICAL ETHICS REVIEWS

Edited by

James M. Humber and Robert F. Almeder

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ETHICS
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and

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Preface

Complementary and Alternative Medicine (CAM) poses numerous challenges to the health-care delivery system that presently dominates in the United States and Canada. Issues relative to these challenges include, but are not limited to, questions involving therapeutic effectiveness, media truthfulness, patients' freedom to choose among treatment options, health insurance coverage, the ability of the current health-care delivery system to meet patients' needs, and governmental approval of alternative medicines. All of these issues, as well as others, are discussed in the essays included in this volume.

For the convenience of our readers, each article in *Biomedical Ethics Reviews* is prefaced by an abstract describing that article's content. The first two articles in the text take opposite sides in the debate over the usefulness of CAM. Stephen Barrett argues that most alternative therapies are worthless; Vimal Patel contends that CAM modalities may well be useful in eradicating some of the problems inimical to the biomedical-based model health-care system currently dominating the American scene. In the next two articles, three lawyers—Grace Monaco, Gilbert Smith and S. Mitchell Weitzman—discuss the issue of insurance coverage for CAM. Monaco and Smith contend that CAM therapies must produce objective and verifiable data on patient benefit in order to qualify for insurance coverage; Weitzman defends a system that ensures access to both CAM and conventional medical therapies. Finally, the last two articles in the text discuss issues relative to specific CAM therapies. Steven Neeley's concern is principally with prayer and spiritual healing; John Crellin examines the challenges CAM poses for the profession of pharmacy.

Alternative Medicine and Ethics is the fifteenth annual volume in a series of texts designed to review and update the literature on issues of central importance in bioethics today. Each

volume in the series is organized around a central theme; the theme for the next volume of *Biomedical Ethics Reviews* will be *Cloning*. We hope our readers will find the present volume of *Biomedical Ethics Reviews* to be both enjoyable and informative, and that they will look forward with anticipation to the publication of *Cloning*.

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Abstract

"Alternative medicine" has become the politically correct term for questionable practices formerly labeled quack and fraudulent. During the past few years, most media reports have contained no critical evaluation and have featured the views of proponents and their satisfied clients. These happenings are part of a general societal trend toward rejection of science as a method of determining truths.

Under the rules of science, proponents who make the claims bear the burden of proof. Instead of subjecting their work to scientific standards, "alternative proponents" would like to change the rules by which they are judged and regulated. Instead of conducting scientific studies, they use anecdotes and testimonials to promote their practices, and political maneuvering to keep regulatory agencies at bay.

To avoid confusion, "alternative" methods should be classified as genuine, experimental, or questionable. Blurring these distinctions enables promoters of quackery to argue that because some practices labeled "alternative" have merit, the rest deserve equal consideration and respect. Enough is known, however, to conclude that most questionable "alternatives" are worthless.

This chapter provides a critical analysis based on more than 25 years of investigation by the author. Each approach it describes has at least one of the following characteristics:

1. *Its rationale or underlying theory has no scientific basis;*
2. *It has not been demonstrated safe and effective by well-designed studies;*

3. *It is deceptively promoted; or*
4. *Its practitioners are not qualified to make appropriate diagnoses.*

Stephen Barrett, MD, is a nationally renowned author, editor, and consumer advocate. Now retired from the practice of psychiatry, he operates a clearinghouse on health frauds and quackery and a web site (http://www.quackwatch.com) devoted to consumer health issues. He is a board member of the National Council Against Health Fraud, a scientific advisor to the American Council on Science and Health, and a fellow and scientific consultant to the Committee for the Scientific Investigation of Claims of the Paranormal (CSICOP). He has edited or coauthored 43 books, including *The Health Robbers: A Close Look at Quackery in America; The Vitamin Pushers: How the "Health Food" Industry Is Selling America a Bill of Goods;* the American Medical Association's *Reader's Guide to "Alternative Health Methods;* and five editions of the college textbook *Consumer Health: A Guide to Intelligent Decisions.* In 1984, he received the FDA Commissioner's Special Citation Award for Public Service in fighting nutrition quackery. In 1986, he was awarded honorary membership in the American Dietetic Association.

"Alternative" Medicine

More Hype Than Hope

Stephen Barrett, M.D.

The *American Heritage Dictionary* defines "buzzword" as "a usually important-sounding word or phrase connected with a specialized field that is used primarily to impress laymen." Promoters of quackery are very adept at using slogans and buzzwords. During the 1970s, they popularized the word "natural" as a magic sales slogan. During the 1980s, the word "holistic" gained widespread use. Today's leading buzzword is "alternative." Until the late 1980s, in standard medical usage, it referred to choices among effective treatments. In some cases they were equally effective (for example, the use of radiation or surgery for certain cancers); in others the expected outcome differed, but there were reasonable tradeoffs between risks and benefits. During recent years, however, the word "alternative" has been applied to a multitude of unsubstantiated approaches that differ from standard medical ones.

To avoid confusion, "alternative" methods should be classified as genuine, experimental, or questionable. *Genuine* alterna-

tives are comparable methods that have met science-based criteria for safety and effectiveness. *Experimental* alternatives are unproven but have a plausible rationale and are undergoing responsible investigation. The most noteworthy is use of a 10%-fat diet for treating coronary heart disease. *Questionable* alternatives are groundless and lack a scientifically plausible rationale. The archetype is homeopathy, which claims that "remedies" so dilute that they contain no active ingredient can exert powerful therapeutic effects. Blurring these distinctions enables promoters of quackery to argue that because some practices labeled "alternative" have merit, the rest deserve equal consideration and respect.

The "alternative movement" is part of a general societal trend toward rejection of science as a method of determining truths. This movement embraces the postmodernist doctrine that science is not necessarily more valid than pseudocience *(1)*. In line with this philosophy, "alternative" proponents assert that scientific medicine (which they mislabel as allopathic, conventional, or traditional medicine) is but one of a vast array of health-care options. Instead of subjecting their work to scientific standards, they would like to change the rules by which they are judged and regulated.

Under the rules of science, proponents who make health claims bear the burden of proof. It is their responsibility to conduct suitable studies and report them in sufficient detail to permit evaluation and confirmation by others. Most "alternative" methods have not been systematically studied. When asked why, their proponents typically say they lack the money to carry out research. However, preliminary research does not require special funding or even take much effort. The principal ingredients are careful observations, detailed record-keeping, and long-term follow-up "to keep score." Proponents of "alternative" methods almost never do any of these things. Some even claim their concepts are not testable by scientific methods.

"Alternative" practitioners typically use anecdotes and testimonials to promote their methods. When someone feels better after having used a product or procedure, it is natural to credit whatever was done. This is unwise, however, because most ailments resolve by themselves and those that persist can have variable symptoms. Even serious conditions can have sufficient day-to-day variation to enable useless methods to gain large followings.

In addition, taking action often produces temporary relief of symptoms because of to a placebo effect. This effect is a beneficial change in a person's condition that occurs in response to a treatment but is caused by the pharmacologic or physical aspects of the treatment. Belief in the treatment is not essential, but the placebo effect may be enhanced by such factors as faith, sympathetic attention, sensational claims, testimonials, and the use of scientific-looking charts, devices, and terminology. Another drawback of individual success stories is that they don't indicate how many failures might occur for each success. People who are not aware of these facts tend to give undeserved credit to "alternative" methods.

The fact that an alternative method may exert a placebo effect that relieves symptoms is not sufficient reason to justify its use. Therapy should be based on the ability to alter abnormal physiology and not on the ability to elicit a less-predictable placebo effect. Placebo therapy is inherently misleading and can make patients believe something is effective when it is not. Without controlled clinical trials, any treatment that is used could receive credit for the body's natural recuperative ability.

Medical "facts" are determined through a process in which hundreds of thousands of scientists share their observations and beliefs. Editors and editorial boards of scientific journals play an important role by screening out invalid findings and enabling significant ones to be published. Expert panels convened by government agencies, professional groups, voluntary health agencies, and other organizations also contribute to this effort. When controversies arise, further research can be devised to settle them.

Gradually, a shared set of beliefs is developed that is considered scientifically accurate.

Many "alternative" approaches are rooted in vitalism, the concept that bodily functions are affected by a vital principle or "life force" distinct from the physical forces explainable by the laws of physics and chemistry and detectable by scientific instrumentation. Practitioners whose methods are based on vitalistic philosophy maintain that diseases should be treated by "stimulating the body's ability to heal itself" rather than by "treating symptoms." Homeopaths, for example, claim that illness is due to a disturbance of the body's "vital force," which they can correct with special remedies, while many acupuncturists claim that disease is due to imbalance in the flow of "life energy" (*chi* or *Qi*), which they can balance by twirling needles in the skin. Many chiropractors claim to assist the body's "Innate Intelligence" by adjusting the patient's spine. Naturopaths speak of "Vis Medicatrix Naturae." Ayurvedic physicians refer to "prana." And so on. The "energies" postulated by vitalists cannot be measured by scientific methods.

Although vitalists often pretend to be scientific, they really reject the scientific method with its basic assumptions of material reality, mechanisms of cause and effect, and testability of hypotheses. They regard personal experience, subjective judgment, and emotional satisfaction as preferable to objectivity and hard evidence.

"Alternative" practitioners often claim that their approaches promote general health and are cost-effective against chronic health problems. However, there is no published evidence that they are more likely than mainstream physicians to persuade their patients to adopt a healthy lifestyle. Nor have any vitalistic approaches been proven effective or cost-effective against any disease. Table 1 lists additional ploys "alternative" promoters use as sales tools.

During the past few years, the news media have publicized "alternative" methods in ways that are causing great public con-

Table 1
Fifteen Ploys Used to Promote "Alternative" Methods[a]

"We really care about you!"
"We treat the whole patient."
"We attack the cause of disease."
"Out treatments have no side effects"
"We treat medicine's failures."
"Think positive!"
"Jump on the bandwagon."
"Our methods are time-tested"
"Backed by scientific studies"
"Take charge of your health!"
"Think for yourself."
"What have you got to lose?"
"If only you had come earlier."
"Science doesn't have all the answers."
"Don't be afraid to experiment."

[a]From: Barrett, S. and Herbert, V. (1994) *The Vitamin Pushers: How the "Health Food" Industry Is Selling America A Bill of Goods.* Prometheus Books, Amherst, NY.

fusion. Most of these reports have contained no critical evaluation and have featured the views of proponents and their satisfied clients. Many have exaggerated the significance of the National Institutes of Health (NIH)'s recently opened Office of Alternative Medicine (OAM). Creation of this office was spearheaded by promoters of questionable cancer therapies who wanted more attention paid to their methods. Most of OAM's advisory panel members have been promoters of "alternative" methods, and none of its publications have criticized any method. In 1994, the OAM's first director resigned, charging that political interference had hampered his ability to carry out OAM's mission in a scientific manner *(2)*. The OAM has funded about 50 studies related to "alternative" methods. However, it remains to be seen whether such research will yield useful results. Even

if it does, the benefit is unlikely to outweigh the publicity bonanza given to questionable methods.

Common Approaches

Each of the approaches described below has one or more of the following characteristics:

1. Its rationale or underlying theory has no scientific basis;
2. It has not been demonstrated safe and/or effective by well-designed studies;
3. It is deceptively promoted; or
4. Its practitioners are not qualified to make appropriate diagnoses.

"Chinese medicine," often called "Oriental medicine" or "traditional Chinese medicine (TCM)," encompasses a vast array of folk medical practices based on mysticism. It holds that the body's vital energy (*chi* or *qi*) circulates through 14 hypothetical channels, called *meridians*, that have branches connected to bodily organs and functions. Illness is attributed to imbalance or interruption of *chi*. Ancient practices, such as **acupuncture** and **Qigong,** are claimed to restore balance by removing the interruptions.

Traditional acupuncture, as now practiced, involves the insertion of stainless steel needles into various body areas. A low-frequency current may be applied to the needles to produce greater stimulation. **Acupressure** (shiatsu) is a technique that uses finger pressure instead of needles. Some states restrict the use of acupuncture to physicians or persons operating under the direct supervision of physicians, whereas others permit laypersons to practice without medical supervision.

The treatment is applied to "acupuncture points," which are said to be located throughout the body. Originally there were 365 such points, corresponding to the days of the year,

but the number identified by proponents during the past 2000 years has increased gradually to over 2000. Some practitioners place needles at or near the site of disease; others select points on the basis of symptoms. In traditional acupuncture a combination of points is usually used. However, the existence of "meridians," "acupuncture points," or *chi* has never been scientifically validated.

Some acupuncturists reject Chinese medicine's trappings and postulate that pain relief occurs through such mechanisms as the production of endorphins (chemicals similar to narcotics). Although acupuncture may relieve pain, such relief tends to be short-lived. The evidence supporting claims that acupuncture is effective consists mostly of practitioners' observations and poorly designed studies. Acupuncture has not been proven to influence the course of any organic disease.

The adverse effects of acupuncture may be far greater than most people realize. A recent survey of 1135 Norwegian physicians revealed 66 cases of infection, 25 cases of punctured lung, 31 cases of increased pain, and 80 other cases with complications. A parallel survey of 197 acupuncturists, who are more apt to see immediate complications, yielded 132 cases of fainting, 26 cases of increased pain, eight cases of pneumothorax, and 45 other adverse results *(3)*.

Qigong is also claimed to influence the flow of vital energy. Internal Qigong involves deep breathing, concentration, and relaxation techniques used by individuals for themselves. External Qigong is performed by "Qigong masters," who claim to cure a wide variety of diseases with energy released from their fingertips. However, scientific investigators of Qigong masters in China have found no evidence of paranormal powers and some evidence of deception. Investigators have observed, for example, that a patient lying on a table about eight feet from a Qigong master moved rhythmically or thrashed about as the master moved his hands. But when she was placed where she could no longer see him, her movements were unrelated to his *(4)*.

The diagnostic process used by TCM practitioners may include questioning (medical history, lifestyle), observations (skin, tongue, color), listening (breath sounds), and pulse-taking. Medical science recognizes only one pulse, corresponding to the heartbeat, which can be felt in the wrist, neck, feet, and various other places throughout the body. TCM practitioners check six alleged pulses at each wrist and identify more than 25 alleged pulse qualities such as "sinking," "slippery," "soggy," "tight," and "wiry." TCM's "pulses" supposedly reflect the type of imbalance, the condition of each organ system, and the status of the patient's "*chi.*"

The herbs prescribed by Chinese medicine practitioners in the United States are not regulated for safety, potency, or effectiveness. There is also the risk that an acupuncturist whose approach to diagnosis is not based on scientific concepts will fail to diagnose a dangerous condition.

The National Council Against Health Fraud has concluded:

1. Acupuncture is an unproven modality of treatment;
2. Its theory and practice are based on primitive and fanciful concepts of health and disease that bear no relationship to present scientific knowledge;
3. Research during the past 20 years has not demonstrated that acupuncture is effective against any disease;
4. Perceived effects of acupuncture are probably due to a combination of expectation, suggestion, counter-irritation, conditioning, and other psychologic mechanisms;
5. The use of acupuncture should be restricted to appropriate research settings;
6. Insurance companies should not be required by law to cover acupuncture treatment;
7. Licensure of lay acupuncturists should be phased out; and
8. Consumers who wish to try acupuncture should discuss their situation with a knowledgeable physician who has no commercial interest *(5)*.

Aromatherapy involves the use of aromatic oils from plants to affect mood or promote health. The oils are administered in small quantities through inhalation, massage, or other applications to the skin. Aromatherapy products include diffusers, lamps, pottery, candles, pendants, earrings, shampoos, skin creams, lotions, bath salts, and shower gels. The aromatic oils are alleged to contain hormones, antibiotics, and antiseptics, and to represent the "life force," "spirit," or "soul" of the plant. Some proponents claim that aromatherapy is a complete medical system that can "revitalize cells," strengthen defense mechanisms, and cure the cause of disease. Although pleasant odors may enhance a person's effort to relax, there is no scientific evidence that they can influence the course of any disease.

Ayurvedic medicine is set of practices promoted by proponents of transcendental meditation (TM). Ayurveda (meaning "life knowledge") is a traditional Indian approach that includes meditation, "purification" procedures, rejuvenation therapies, herbal and mineral preparations, exercises, and dietary advice based on "body type." Its origin is traceable to four Sanskrit books called the *Vedas*—the oldest and most important scriptures of India, shaped sometime before 200 BCE. These books attributed most disease and bad luck to demons, devils, and the influence of stars and planets. Ayurveda's basic theory states that the body's functions are regulated by three "irreducible physiological principles" called doshas, whose Sanskrit names are *vata*, *pitta*, and *kapha*. Like the "sun signs" of astrology, these terms are used to designate body types as well as the traits that typify them. Like astrologic writings, ayurvedic writings contain long lists of supposed physical and mental characteristics of each constitutional type. Through various combinations of vata, pitta, and kapha, ten body types are possible. However, one's *doshas* (and therefore one's body type) can vary from hour to hour and season to season.

Ayurvedic proponents claim that the symptoms of disease are always related to "imbalance" of the doshas, which can be determined by feeling the patient's wrist pulse or completing a

questionnaire. Some proponents claim that the pulse can be used to detect diabetes, cancer, musculoskeletal disease, asthma, and "imbalances at early stages when there may be no other clinical signs and when mild forms of intervention may suffice" *(6)*. "Balance" is supposedly achieved through a multitude of procedures and products, many of which are said to be specific for specific body types. The full Maharishi Ayur-Ved program for "creating healthy individuals and a disease-free society" has 20 components: development of higher states of consciousness through advanced meditation techniques, use of primordial sounds, correction of "the mistake of the intellect," strengthening of emotions, Vedic structuring of language, music therapy, enlivening of the senses, pulse diagnosis, psychophysiological integration, neuromuscular integration, neurorespiratory integration, purification (to remove "impurities due to faulty diet and behavioral patterns"), dietary measures, herbal food supplements, other herbal preparations, daily behavioral routines, prediction of future imbalances, religious ceremonies, nourishing the environment, and promoting world health and world peace. Most of these cost several hundred dollars, but some cost thousands and require the services of an ayurvedic practitioner *(7)*.

TM is a technique in which the meditator sits comfortably with eyes closed and mentally repeats a Sanskrit word or sound (mantra) for 15 to 20 minutes, twice a day. It is alleged to help people think more clearly, improve their memory, recover immediately from stressful situations, reverse their aging process, and enjoy life more fully. Proponents also claim that "stress is the basis of all illness" and that TM is "the single most effective thing you can do to improve all aspects of health and to increase inner happiness and learning ability"*(8)*.

Deepak Chopra, MD, a leading ayurveda proponent, claims that "If you have happy thoughts, then you make happy molecules. On the other hand, if you have sad thoughts, and angry thoughts, and hostile thoughts, then you make those molecules which may depress the immune system and make you more sus-

ceptible to disease"*(9)*. Chopra promises "perfect health" to those who can harness their consciousness as a healing force. Meditation may temporarily relieve stress—as would many types of relaxation techniques—but the rest of these claims have no scientific basis.

Chelation therapy is a series of intravenous administrations of a synthetic amino acid (EDTA) plus various other substances. Proponents claim that chelation can reverse atherosclerosis, is an effective alternative to bypass surgery, and works against many other diseases. However, there is no scientific evidence that chelation therapy modifies any disease process. Recent well-designed studies have demonstrated that chelation therapy is not effective against intermittent claudication, a condition in which circulation to the legs is impaired. It is safe to assume that improvements reported by heart-disease patients undergoing chelation therapy are due to improvements in lifestyle (smoking cessation, dietary change, appropriate exercise, and weight control), the same measures recommended by scientific practitioners.

Chiropractic encompasses a large number of practices, most of which are related to the false premise that spinal problems are the cause, or underlying cause, of most ailments. Although virtually all chiropractors manipulate the spine as their primary method of treatment, their rationale and techniques vary considerably.

D. D. Palmer, chiropractic's founder, postulated that the body's "vital force," which he termed "Innate," expressed itself through the nervous system. Chiropractors who cling strictly to this notion allege that misalignments ("subluxations") of the vertebra cause most illnesses by interfering with the flow of "nerve energy" to body organs. Most chiropractors acknowledge the importance of other factors in disease but tend to regard mechanical disturbances of the nervous system as an underlying cause. In addition, many chiropractors engage in unscientific diagnostic procedures (primarily hair analysis and applied kinesiology), prescribe inappropriate food supplements, and utilize homeopathic remedies. A small percentage of chiropractors

denounce Palmer's theories, spurn unscientific practices, and confine their practice to musculoskeletal problems.

Although chiropractic schools are accredited, they do not provide the depth of diagnostic and therapeutic training that physicians receive *(10)*. Whereas most medical school faculties are large and contain experts in every aspect of medical practice, chiropractic schools have few or no physicians on their faculty. Although the patients studied by medical students encompass the full range of disease, the vast majority seen by chiropractic students seek help for musculoskeletal problems. Although some of their courses are based on standard medical textbooks, chiropractic students lack the experiences needed to make the information meaningful. Chiropractic instruction in such subjects as pediatrics, obstetrics, and gynecology is usually limited to the classroom, with little or no actual patient contact and no experience with hospitalized patients. One school, for example, has used only rubber models to teach students how to perform pelvic and rectal examinations. Moreover, since much of chiropractic is based on a false premise, neither length of study nor accreditation of its schools can ensure that those who graduate will practice competently.

Some chiropractic schools require their students to recruit patients. This problem was highlighted in 1996 when a jury in Kansas City, MO, awarded $93,000 in actual damages plus $45,000 in punitive damages to a 27-year-old woman who charged that Cleveland Chiropractic College had committed fraud by failing to tell her that she would be responsible for recruiting her own patients during the clinical phase of chiropractic training. The woman testified that to meet quotas, students were required to lure or entice friends and family into the clinic, and then charge them for chiropractic treatment that they did not need. A former instructor testified that between 1991 and 1995 she knew of no student who met the clinical requirements solely by relying on patients provided by the clinic *(11)*.

Chiropractic has received considerable favorable publicity since studies by the RAND Corporation and the US Agency for

Health Care Policy and Research (AHCPR) concluded that spinal manipulation may be appropriate for certain cases of low-back pain. However, most of the research upon which this conclusion was based was done by medical doctors and physical therapists and does not reflect what takes place in most chiropractic offices. The AHCPR report contains no mention of chiropractic in its text. An expert review team subsequently identified only eight randomized controlled studies performed by chiropractors between January 1966 and June 1995. These experts concluded:

1. All of the studies has significant flaws in their design;
2. There was no convincing evidence that chiropractic manipulation is effective for acute or chronic low back pain; and
3. Before further studies are attempted, chiropractic researchers should establish uniform guidelines for performing and reporting clinical trials *(12)*.

Many chiropractors urge everyone to have their spine checked weekly or monthly for "preventative maintenance." There is no scientific evidence supporting this practice *(13)*. Some chiropractors take full-spine X-rays of all or most of their patients. This procedure has little or no diagnostic value and involves a large amount of radiation.

Consumers who wish to have chiropractic care should choose a chiropractor whose practice is limited to treating musculoskeletal problems and whose work is respected by local medical doctors. If spinal manipulation can help, it generally does so within two weeks. It is wise to avoid chiropractors who prescribe dietary supplements, homeopathic remedies, or herbal products for the treatment of disease or who sell any of these products in their offices. For dietary advice, the best sources are physicians and registered dietitians.

Clinical ecology, which proponents also misrepresent as "environmental medicine," is not a recognized medical specialty. It is based on the notion that multiple common symptoms are triggered by hypersensitivity to common foods and chemicals.

Proponents typically suggest that the immune system is like a barrel that continually fills with chemicals until it overflows, signaling the presence of disease. However, some also say that "immune system dysregulation" can be triggered by a single serious episode of infection, stress, or chemical exposure. Potential stressors include practically everything that modern humans encounter, such as urban air, diesel exhaust, tobacco smoke, fresh paint or tar, organic solvents and pesticides, certain plastics, newsprint, perfumes and colognes, medications, gas used for cooking and heating, building materials, permanent press and synthetic fabrics, household cleaners, rubbing alcohol, felt-tip pens, cedar closets, tap water, and electromagnetic forces.

Clinical ecologists typically base their diagnoses on "provocation-neutralization" testing. In this test, the patient reports symptoms that develop within 10 minutes after various concentrations of suspected substances are administered under the tongue or injected into the skin. If any symptoms occur, the test is considered positive and lower concentrations are given until a dose is found that "neutralizes" the symptoms.

Treatment requires avoidance of suspected substances and involves lifestyle changes that can range from minor to extensive. Generally, patients are instructed to modify their diet and to avoid such substances as scented shampoos, aftershave products, deodorants, cigarette smoke, automobile exhaust fumes, and clothing, furniture, and carpets that contain synthetic fibers. Extreme restrictions can involve staying at home for months or avoiding physical contact with family members. In many cases the patient's life becomes centered around the illness.

Researchers at the University of California have demonstrated that provocation-neutralization testing is not valid. In a double-blind study, each of 18 patients received three injections of suspected food extracts and nine of dilute salt water over a three-hour period. The tests were carried out in the offices of proponents who had been treating the patients. In nonblinded tests, these patients had consistently reported symptoms when

exposed to food extracts and no symptoms when given salt-water injections. But during the experiment, the patients reported as many symptoms following one type of injection as they did after the other, indicating that their symptoms were nothing more than placebo reactions. The symptoms included itching of the nose, watery or burning eyes, plugged ears, a feeling of fullness in the ears, ringing ears, dry mouth, scratchy throat, an odd taste in the mouth, fatigue, headache, nausea, dizziness, abdominal discomfort, tingling of the face or scalp, tightness or pressure in the head, disorientation, difficulty breathing, depression, chills, coughing, nervousness, intestinal gas or rumbling, and aching legs. Clinical ecologists also claim that "neutralizing" doses of offending allergens can relieve the patient's symptoms. However, the patients who were treated during the experiment had equivalent responses to extracts and salt water *(14)*.

The American Academy of Allergy, Asthma and Immunology (AAAAI), the nation's largest professional organization of allergists, has warned:

> Although the idea that the environment is responsible for a multitude of health problems is very appealing, to present such ideas as facts, conclusions, or even likely mechanisms without adequate support, is poor medical practice *(15)*.

Colonic irrigation is performed by passing a rubber tube into the rectum for a distance of up to twenty or thirty inches. Warm water is pumped in and out through the tube, a few pints at a time, typically using 20 or more gallons. Some practitioners add herbs, coffee, or other substances to the water. The procedure is said to "detoxify" the body. Its advocates claim that, as a result of intestinal stasis, intestinal contents putrefy, and toxins are formed and absorbed, which causes chronic poisoning of the body.

This "autointoxication" theory was popular around the turn of the century but was abandoned by the scientific community during the 1930s. No such "toxins" have ever been identified, and

careful observations have shown that individuals in good health can vary greatly in bowel habits. Proponents may also suggest that fecal material collects on the lining of the intestine and causes trouble unless removed by laxatives, colonic irrigation, special diets, and/or various herbs or food supplements that "cleanse" the body. The falsity of this notion is obvious to doctors who perform intestinal surgery or peer within the large intestine with a diagnostic instrument. Fecal material does not adhere to the intestinal lining.

Colonic irrigation is not only therapeutically worthless but can cause fatal electrolyte imbalance. Cases of death due to intestinal perforation and infection (from contaminated equipment) have also been reported.

Craniosacral therapy, also called craniopathy and cranial osteopathy, is based on the notion that bones of the skull are moveable and can be manipulated. Some practitioners claim to attune themselves to the patient's "rhythm" while holding the patient's skull in their hands. Some claim to improve the flow of "life energy," thereby curing or preventing a wide variety of health problems. Some claim to remove blockages to the flow of cerebrospinal fluid. Some claim to realign the skull bones. Actually, the bones of the skull fuse early in life and cannot be moved independently.

Electrodiagnosis involves the use of various devices purported to diagnose and treat "energy imbalances" alleged to signify disease. The procedure, also called Electroacupuncture according to Voll (EAV), was initiated during the 1970s by a German physician who developed the first model of the device. Subsequent models include the *Vega, Dermatron, Accupath 1000,* and *Interro.* Proponents claim these devices measure disturbances in the body's flow of "electro-magnetic energy" along "acupuncture meridians." Actually, they are little more than fancy galvanometers that measure electrical resistance of the patient's skin when touched by a probe. One wire from the device goes to a brass cylinder covered by moist gauze, which the patient holds

in one hand. A second wire is connected to a probe, which the operator touches to "acupuncture points" on the patient's other hand or foot. This completes a low-voltage circuit and the device registers the flow of current. The information is then relayed to a gauge that provides a numerical readout. The size of the number actually depends on how hard the probe is pressed against the patient's skin. The "treatment" selected depends on the scope of the practitioner's practice and may include acupuncture, dietary change, vitamin supplements and/or homeopathic remedies. Some EAV devices have been seized by state and federal regulators, but hundreds remain in use.

Herbalism is practiced mainly by naturopaths, chiropractors, acupuncturists, iridologists, and unlicensed "herbalists," many of whom prescribe herbs for virtually every health problem. Although some attempt to base their prescriptions on research findings, others are guided by such perceptions as "astrological influences" and the "Doctrine of Signatures" (the ancient belief that the form and shape of a drug source determine its therapeutic value). Many herbs contain hundreds or even thousands of chemicals that have not been completely cataloged. Although some of these may turn out to be useful as therapeutic agents, others could well prove toxic. Most herbal products sold in the United States are not standardized, which means that determining the exact amounts of their ingredients can be difficult or impossible. With safe and effective medicines available, treatment with herbal products makes little sense. Moreover, many herbal practitioners are not physicians and lack adequate training in the diagnosis and treatment of disease.

Homeopathy is based on a 200-year-old notion that if large amounts of a substance can produce symptoms in a healthy individual, tiny amounts can cure diseases having those symptoms. This idea is scientifically unsupportable.

Homeopathic products are made from minerals, plant substances, and several other sources. If the original substance is soluble, one part is diluted with either nine or 99 parts of distilled

water and/or alcohol and shaken vigorously; if insoluble, it is finely ground and pulverized in similar proportions with powdered lactose (milk sugar). One part of the diluted medicine is diluted, and the process is repeated until the desired concentration is reached. Dilutions of 1 to 10 are designated by the Roman numeral X (1X = 1/10, 3X = 1/1000, 6X = 1/1,000,000). Similarly, dilutions of 1 to 100 are designated by the Roman numeral C (1C = 1/100, 3C = 1/1,000,000, and so on). Most remedies today range from 6X to 30X, but many products of 30C or more are marketed.

A 30X dilution means that the original substance has been diluted 10^{30} times. Assuming that a cubic centimeter of water contains fifteen drops, 10^{30} is greater than the number of drops of water that would fill a container more than fifty times the size of the Earth. Becuase the least amount of a substance in a solution is one molecule, a 30C solution would have to have at least one molecule of the original substance dissolved in a minimum of 1060 molecules of water. This would require a container more than thirty billion times the size of the Earth.

Occillococcinum, a 200C product "for the relief of colds and flu-like symptoms," involves "dilutions" that are even more far-fetched. Its "active ingredient" is prepared by incubating small amounts of a freshly killed duck's liver and heart for 40 days. The resultant solution is then filtered, freeze-dried, rehydrated, repeatedly diluted, and impregnated into sugar granules. If a single molecule of the original substance were to survive the dilution, its concentration would be 1 in 100^{200}. The number 100^{200} is vastly greater than the estimated number of molecules in the universe. *U.S. News & World Report* has noted that only one duck per year has been used to manufacture the product, which had total sales of $20 million in 1996.

Actually, the laws of chemistry state that there is a limit to the dilution that can be made without losing the original substance altogether. This limit, called Avogadro's number (6.023×10^{23}), corresponds to homeopathic potencies of 12C or 24X

(1 part in 10^{24}). Proponents acknowledge that there is virtually no chance that even one original molecule would remain after extreme dilutions. But they claim that the vigorous shaking or pulverizing with each step of dilution leaves behind a "spirit-like" essence that cures by reviving the body's "vital force." This notion is unsubstantiated and clashes with the laws of physics. Moreover, if it were true, any molecule in the diluting substance might imprint an "essence" that could exert powerful (and unpredictable) medicinal effects. Although the Food and Drug Administration (FDA) permits the sale of homeopathic remedies, it does not recognize them as effective.

Iridology is based on the notion that each area of the body is represented by a corresponding area in the iris of the eye (the colored area surrounding the pupil). Iridologists claim that states of health and disease can be diagnosed according to the color, texture, and location of various pigment flecks in the eye. Iridology practitioners purport to diagnose "imbalances" and treat them with vitamins, minerals, herbs, and similar products. They may also claim that the eye markings can reveal a complete history of past illnesses as well as previous treatment.

Most iridology practitioners are chiropractors and naturopaths, but laypersons who do "nutrition counseling" also are involved. Bernard Jensen, DC, the leading American iridologist, states that "Nature has provided us with a miniature television screen showing the most remote portions of the body by way of nerve reflex responses" *(16)*. He also claims that iridology analyses are more reliable and "offer much more information about the state of the body than do the examinations of Western medicine." However, in two large studies, Jensen and seven other prominent iridologists could not distinguish between patients who had kidney *(17)* or gallbladder *(18)* disease and those who were healthy. Nor did they agree with each other about which was which.

Macrobiotics is a quasireligious approach centered around a semivegetarian diet claimed to improve health and prolong

life. Proponents suggest that the diet is effective in preventing and treating cancer, AIDS, and other serious diseases. There is no scientific evidence to support these claims. Macrobiotic proponents base their recommendations for foods on the amount of "yin" or "yang" (alleged "energy modes") rather than nutrient content. Macrobiotic practitioners may base their recommendations on pulse diagnosis and other unscientific procedures related to Chinese medicine. These include "ancestral diagnosis," "astrological diagnosis," "aura and vibrational diagnosis," "environmental diagnosis" (including consideration of celestial influences" and tidal motions), and "spiritual diagnosis" (an eval-uation of "atmospheric vibrational conditions" to identify spiritual influences, including memories and "visions of the future").

Today's leading proponent is Michio Kushi, founder and president of the Kushi Institute in Becket, MA. According to Institute publications, the macrobiotic way of life should include chewing food at least 50 times per mouthful (or until it becomes liquid), not wearing synthetic or woolen clothing next to the skin, avoiding long hot baths or showers, having large green plants in your house to enrich the oxygen content of the air, and singing a happy song every day. Kushi claims that cancer is largely caused by improper diet, thinking, and way of life, and can be influenced by changing these factors. He recommends "yin foods" for cancers caused by excess yang, and "yang foods" for tumors that are predominantly yin. His books contain case histories of people whose cancers have supposedly disappeared after they adopted macrobiotic eating. However, the only reports of efficacy are testimonials by patients, many of whom received conventional cancer therapy. The diet itself can cause cancer patients to undergo serious weight loss.

Some versions of macrobiotic diets contain adequate amounts of nutrients, but others do not. Studies of children living in several macrobiotic communities have found that they tended to be smaller, shorter, and to weigh less than children fed normal

diets. Deficiencies of vitamin B_{12}, iron, and vitamin D have also been reported.

Naturopathy is based on the belief that the cause of disease is violation of nature's laws. Naturopaths claim to remove the underlying causes of disease and to stimulate the body's natural healing processes. They state that diseases are the body's effort to defend itself and that cures result from increasing the patient's "vital force" by ridding the body of waste products and "toxins." Like some chiropractors, many naturopaths believe that virtually all ailments fall within the scope of their practice. Naturopathic treatments can include "natural food" diets, vitamins, herbs, tissue minerals, cell salts, manipulation, massage, exercise, diathermy, colonic enemas, acupuncture, and homeopathy. Although naturopaths claim that they stress prevention of disease, they tend to oppose immunization procedures.

Natural hygiene is an offshoot of naturopathy that emphasizes fasting, a raw-food diet of vegetables, fruits, and nuts, and food-combining, which is a dietary practice based on the incorrect notion that certain food combinations can cause or correct ill health. Natural hygienists oppose immunization, fluoridation, and food irradiation and eschew most forms of medical treatment.

Orthomolecular therapy is defined by its proponents as "the treatment of disease by varying the concentrations of substances normally present in the human body." It dates back to the early 1950s when a few psychiatrists began adding massive doses of nutrients to their treatment of severe mental problems. The original substance was vitamin B_3 (nicotinic acid or nicotinamide), and the therapy was termed "megavitamin therapy." Later the treatment regimen was expanded to include other vitamins, minerals, hormones, and diets, any of which may be combined with conventional drug therapy and electroshock treatments. A few hundred physicians now use this approach to treat a wide variety of conditions, both mental and physical.

The human body has limited capacity to use vitamins in its metabolic activities. When vitamins are consumed in excess of

the body's physiological needs, they function as drugs rather than vitamins. A few situations exist in which high doses of vitamins are known to be beneficial, but they must still be used with caution because of potential toxicity. For example, large doses of niacin can be very useful as part of a comprehensive, medically supervised program for controlling abnormal blood cholesterol levels. "Orthomolecular" practitioners go far beyond this, however, by prescribing large amounts of supplements to all or most of the patients they treat.

Reflexology, also called zone therapy, is based on beliefs that each body part is represented on the hands and feet and that pressing on the hands and feet can have therapeutic effects in other parts of the body. Proponents claim that the body is divided into 10 zones that begin or end in the hands and feet, and that each organ or body part is "represented" on the hands or feet. Proponents also claim that abnormalities can be diagnosed by feeling the feet and that pressing each area can stimulate the flow of energy, blood, nutrients, and nerve impulses to the corresponding body zone. The pathways postulated by reflexologists have not been anatomically demonstrated.

Most reflexologists claim that their foot massages can relieve stress, which presumably is correct but does not require the services of a "certified reflexologist" for $35–$100 per session. Many practitioners claim foot reflexology can cleanse the body of toxins, increase circulation, assist in weight loss, and improve the health of organs throughout the body. Some claim that reflexology is effective against a large number of serious diseases. There is no scientific support for these assertions.

Therapeutic touch is a method in which the hands are used to "direct human energies to help or heal someone who is ill." Proponents claim that healers can detect and correct "energy imbalances" by stroking the body or placing their hands above the afflicted part. Healing supposedly can result from a transfer of "excess energy" from healer to patient. Neither the forces involved nor the alleged therapeutic benefits have been demon-

strated by scientific testing. It is safe to assume that any reactions to the procedure are psychological responses to the "laying on of hands." As taught by its leading proponent, TT involves four steps:

1. "Centering," a meditative process said to align the healer with the patent's energy level;
2. "Assessment," said to be performed by using one's hands to detect forces emanating from the patient;
3. "Unruffling the field," said to involve sweeping "stagnant energy" downward to prepare for energy transfer; and
4. Transfer of "energy" from practitioner to patient. "Noncontact therapeutic touch" is done the same way, except that the "healer's" hands are held a few inches away from the body.

There is no scientific evidence that the "energy transfer" postulated by proponents actually occurs. In 1996, Linda Rosa, RN, published a critique of all 131 of the studies related to TT she could locate in nursing journals and elsewhere. She concluded: "The more rigorous the research design, the more detailed the statistical analysis, the less evidence that there is any observed—or observable—phenomenon"*(19)*.

Rosa's 10-year-old daughter recently demonstrated that 21 TT practitioners could not detect the presence of her hand near theirs. During the experiment, the practitioners rested their forearms and hands, palms up, on a flat surface, approximately 10–12 inches apart. The child then held her right hand, palm down, three to four inches above one of the subject's palms. A cardboard screen and a towel were used to prevent the practitioners from seeing which hand was selected. Each subject was asked 10 or 20 times to state which of her own hands the child's hand was near. The results were no better than chance *(20)*.

Fad Diagnoses

Some "alternative" practitioners misdiagnose large numbers of their patients with one or more conditions considered rare

or even nonexistent by scientific practitioners. Some of these diagnoses are based on the patient's history (typically including fatigue and other common emotionally related symptoms), whereas others are based on inappropriate or misinterpreted laboratory tests.

Many of these practitioners describe themselves as practicing "holistic," "complementary," or "nutritional" medicine and prescribe "nutritional" products to virtually every patient they see. Their "fad diagnoses" include hypoglycemia (a real but uncommon condition in which blood sugar is low); hypothyroidism (a real but uncommon condition in which the thyroid gland is underactive); "Candidiasis hypersensitivity" (a nonexistent condition sometimes referred to as "yeast allergy"); " "environmental illness" (a nonexistent condition also called "multiple chemical sensitivity"); and "mercury amalgam toxicity." Chronic fatigue syndrome, Lyme disease, and "parasites," although not rare, are also overdiagnosed by such practitioners. They may also claim that large numbers of Americans have multiple symptoms caused by undiagnosed food allergies.

"Mercury-amalgam toxicity" is diagnosed by a few hundred dentists who falsely claim that the mercury in silver–mercury fillings is toxic and causes a wide range of illnesses. These dentists recommend replacing these fillings with other materials, which can cost thousands of dollars. The American Dental Association considers this practice unethical.

Questionable Approaches to Cancer

The American Cancer Society (ACS) defines questionable methods as lifestyle practices, clinical tests, or therapeutic modalities promoted for *general* use for the prevention, diagnosis, or treatment of cancer and that are, on the basis of careful review by scientists and/or clinicians, deemed to have no real evidence of value *(21)*. Promoters claim that their methods are

natural and nontoxic and that standard therapies are highly dangerous. They typically explain their approaches in commonsense terms that appear to offer patients an active role:

1. Cancer is a symptom, not a disease;
2. Symptoms are caused by diet, stress, or environment;
3. Proper fitness, nutrition, and mental attitude allow biologic and mental defense against cancer; and
4. Conventional therapy weakens the body's reserves, treats the symptoms rather than the disease. None of these assertions is accurate. The methods most publicized include the following.

Antineoplastons

Stanislaw R. Burzynski, MD, PhD, has given the name "antineoplastons" to substances he claims can "normalize" cancer cells that are constantly being produced within the body. He has published many papers stating that antineoplastons extracted from urine or synthesized in his laboratory have proven effective against cancer in laboratory experiments. He also claims to have helped many people with cancer get well. Saul Green, PhD, a biochemist who worked for many years at Memorial Sloan-Kettering Hospital doing research into the mechanisms and treatment of cancer, has analyzed Burzynski's publications and found no evidence that any of the substances Burzynski calls "antineoplastons" have been proven to "normalize" tumor cells *(22)*. In 1995, a federal grand jury indicted Burzynski for criminal contempt of court, mail fraud, and marketing an unapproved drug in interstate commerce. The indictment charged that he had billed insurance companies using procedure codes for chemotherapy at his clinic, even though his treatment was not chemotherapy and was administered elsewhere by the patient. The indictment also stated that Burzynski and his clinic had grossed more than $40 million between 1988 and 1994 through producing, prescribing, and selling a drug that lacked FDA approval.

CanCell

CanCell, originally called Entelev, is a liquid claimed to "lower the voltage of the cell structure by about 20%," causing cancer cells to "digest" and be replaced with normal cells. CanCell has also been promoted for the treatment of AIDS, amyotrophic lateral sclerosis, multiple sclerosis, Alzheimer's disease, "extreme cases of emphysema and diabetes," and several other diseases. In 1989, the FDA reported that CanCell contained inositol, nitric acid, sodium sulfite, potassium hydroxide, sulfuric acid, and catechol. Subsequently, its promoters claimed to be modifying the formulation to make it more effective. They have also claimed that CanCell can't be analyzed because it varies with atmospheric vibrations and keeps changing its energy. Labor-atory tests conducted by the National Cancer Institute Laboratory between 1978 and 1991 found no evidence that CanCell was effective against cancer. The FDA has obtained an injunction forbidding its distribution to patients.

Essiac

Essiac is an herbal remedy that was prescribed and promoted for about 50 years by Rene M. Caisse, a Canadian nurse who died in 1978. Shortly before her death, she turned over the formula and manufacturing rights to the Resperin Corporation, a Canadian company that has provided it to patients under a special agreement with Canadian health officials. Several reports state that the formula contains burdock, Indian rhubarb, sorrel, and slippery elm, but there may be additional ingredients. Essiac tea claimed to be Caisse's original formulation is also marketed in the United States. Several animal tests using samples of Essiac have shown no antitumor activity, nor did a review of data on 86 patients performed by the Canadian federal health department during the early 1980s.

Gerson Method

Proponents of the Gerson diet claim that cancer can be cured only if toxins are eliminated from the body. They recommend "detoxification" with frequent coffee enemas and a low-sodium diet that includes more than a gallon a day of juices made from fruits, vegetables, and raw calf's liver. Gerson protocols have also included liver extract injections, ozone enemas, "live cell therapy," thyroid tablets, royal jelly capsules, linseed oil, castor oil enemas, clay packs, laetrile, and vaccines made from influenza virus and killed *Staphylococcus aureus* bacteria.

The Gerson method was developed by Max Gerson, a German-born physician who emigrated to the United States in 1936 and practiced in New York City until his death in 1959. Still available at a clinic near Tijuana, Mexico, Gerson therapy is actively promoted by his daughter, Charlotte Gerson, through lectures, talk show appearances, and publications of the Gerson Institute in Bonita, CA.

In 1947, the National Cancer Institute (NCI) reviewed 10 cases selected by Dr. Gerson and found his report unconvincing. That same year, a committee appointed by the New York County Medical Society reviewed records of 86 patients, examined 10 patients, and found no evidence that the Gerson method had value in treating cancer. An NCI analysis of Dr. Gerson's book *A Cancer Therapy: Results of Fifty Cases* concluded in 1959 that most of the cases failed to meet the criteria (such as histologic verification of cancer) for proper evaluation of a cancer case. A recent review of the Gerson treatment rationale concluded:

1. The "poisons" Gerson claimed to be present in processed foods have never been identified;
2. Frequent coffee enemas have never been shown to mobilize and remove poisons from the liver and intestines of cancer patients;
3. There is no evidence that any such poisons are related to the onset of cancer;

4. There is no evidence that a "healing" inflammatory reaction exists that can seek out and kill cancer cells *(23)*.

Charlotte Gerson claims that treatment at the clinic has produced high cure rates for certain cancers. In 1986, however, a Gerson publicist admitted that patients had not been monitored after they left the facility. A naturopath who visited the Gerson Clinic in 1983 was able to track 21 patients over a five-year period (or until death) through annual letters or phone calls. At the five-year mark, only one was still alive (but not cancer-free); the rest had succumbed to their cancer *(24)*.

Hoxsey Treatment

Naturopath Harry Hoxsey promoted an herbal treatment consisting of an externally used paste or powder and a tonic taken orally. The external preparations contained corrosive agents such as arsenic sulfide. The internal medicine, said to be adjusted on a case-by-case basis, contained potassium iodide and several herbs. Hoxsey said that the formulas were developed in 1840 by his great grandfather and passed to him by his father while the latter was dying of cancer.

Hoxsey's treatment was offered at clinics in the United States from 1924 until repeated clashes with the FDA led him to close his main clinic in Dallas in the late 1950s. Since 1963, it has been available only at a clinic in Tijuana, Mexico, operated by Hoxsey's former chief nurse, Mildred Nelson. Hoxsey himself contracted prostate cancer in 1967 and underwent surgery after treating himself unsuccessfully with his tonic. Most of the herbs in the tonic have been tested for antitumor activity in cancer, with negligible results for a few and no results for the others. Some of these herbs, most notably pokeroot, have toxic side effects. The NCI evaluated case reports submitted by Hoxsey and concluded that no assessment was possible because the records did not contain adequate information. Hoxsey died in 1974.

Hydrazine Sulfate

In the mid-1970s hydrazine sulfate was proposed for treating the progressive weight loss and body deterioration characteristic of advanced cancer. Based on animal data and preliminary human studies, it has also been claimed to cause tumor regression and subjective improvement in patients. However, three recent trials sponsored by the National Cancer Institute found that hydrazine sulfate was no better than a placebo. The trials involved a total of 636 patients with three types of cancer. In one study nerve damage occurred more often and the quality of life was significantly worse in the hydrazine sulfate group.

"Hyperoxygenation" Therapy

Also called "bio-oxidative therapy" and "oxidative therapy," "hyperoxygenation" therapy is based on the erroneous concept that cancer is caused by oxygen deficiency and can be cured by exposing cancer cells to more oxygen than they can tolerate. The most touted agents are hydrogen peroxide, germanium sesquioxide, and ozone. Although these compounds have been the subject of legitimate research, there is little or no evidence that they are effective for the treatment of any serious disease, and each has demonstrated potential for harm. Germanium products have caused irreversible kidney damage and death. The FDA has banned their importation and seized products from several U.S. manufacturers.

Immunoaugmentative Therapy (IAT)

IAT was developed by Lawrence Burton, PhD, a zoologist who claimed to treat cancer patients by manipulating an immune defense system that he postulated. He claimed to accomplish this by injecting protein extracts isolated with processes he had patented. However, experts believe that the substances Burton claimed to use cannot be produced by these procedures and have not been demonstrated to exist in the human body. NCI scientists

who analyzed treatment materials given to several patients concluded that the materials were dilute solutions of ordinary blood proteins, primarily albumin. None contained Burton's postulated components. Burton did not publish detailed clinical reports, divulge to the scientific community the details of his methods, publish meaningful statistics, conduct a controlled trial, or provide independent investigators with specimens of his treatment materials for analysis. During the mid-1980s, several of his patients developed serious infections following IAT. Burton died in 1993, but the clinic is still operating.

Kelley Metabolic Therapy

In the 1960s, a dentist named William Donald Kelley developed a program for cancer patients that involved dietary measures, vitamin and enzyme supplements, and computerized "metabolic typing." Kelley classified people as "sympathetic dominant," "parasympathetic dominant," or metabolically "balanced" and made dietary recommendations for each type. He claimed that his "Protein Metabolism Evaluation Index" could diagnose cancer before it was clinically apparent and that his "Kelley Malignancy Index" could detect "the presence or absence of cancer, the growth rate of the tumor, the location of the tumor mass, prognosis of the treatment, age of the tumor and the regulation of medication for treatment."

In 1970, Kelley was convicted of practicing medicine without a license after witnesses testified that he had diagnosed lung cancer on the basis of blood from a patient's finger and prescribed dietary supplements, enzymes, and a diet as treatment. In 1976, following court appeals, his dental license was suspended for five years. However, he continued to promote his methods until the mid-1980s.

Similar treatment is provided today by Nicholas Gonzales, MD, of New York City, who claims to have analyzed Kelley's records and drafted a book about his findings. The manuscript was never published, but experts who evaluated its chapter on

50 cases found no evidence of benefit *(25)*. Gonzales says that he offers "10 basic diets with 90 variations" and typically prescribes coffee enemas and "up to 150 pills a day in 10 to 12 divided doses."

Laetrile

Laetrile, which achieved great notoriety during the 1970s and early 1980s, is the trade name for a synthetic relative of amygdalin, a chemical in the kernels of apricot pits, apple seeds, bitter almonds, and several other fruits and nuts. Many laetrile promoters have called it "vitamin B_{17}" and falsely claimed that cancer is a vitamin deficiency disease that laetrile can cure. Claims for laetrile's efficacy have varied considerably. First it was claimed to prevent and cure cancer. Then it was claimed not to cure, but to "control" cancer while giving patients an increased feeling of well being. More recently, laetrile has been claimed to be effective, not by itself, but as one component of "metabolic therapy" (*see* section on Metabolic Therapy).

Laetrile was first used to treat cancer patients in California in the 1950s. According to proponents, it kills tumor cells selectively while leaving normal cells alone. Although laetrile has been promoted as safe and effective, clinical evidence indicates that it is neither. When broken down by enzymes in the body, it forms glucose, benzaldehyde, and a cyanide compound. Some cancer patients treated with laetrile have suffered nausea, vomiting, headache and dizziness, and a few have died from cyanide poisoning. Laetrile has been tested in at least 20 animal-tumor models and found to have no benefit either alone or together with other substances. Several case reviews have found no benefit for the treatment of cancer in humans.

In response to political pressure, a clinical trial was begun in 1982 by the Mayo Clinic and three other U.S. cancer centers under NCI sponsorship. Laetrile and "metabolic therapy" were administered as recommended by their promoters. The patients had advanced cancer for which no proven treatment was known. Of 178 patients, not one was cured or stabilized, and none had

any lessening of any cancer-related symptoms. The median survival rate was about five months from the start of therapy. In those still alive after seven months, tumor size had increased. Several patients experienced symptoms of cyanide toxicity or had blood levels of cyanide approaching the lethal range *(26)*. Few sources of laetrile are now available within the United States, but several Mexican clinics still utilize it.

Livingston-Wheeler Regimen

Virginia C. Livingston, MD, who died in 1990, postulated that cancer is caused by a bacterium she called *Progenitor cryptocides,* which invades the body when "immunity is stressed or weakened." She claimed to counter this by strengthening the body's immune system with vaccines (including one made from the patient's urine); "detoxification" with enemas; digestive enzymes; a vegetarian diet that avoided chicken, eggs, and sugar; vitamin and mineral supplements; visualization; and stress reduction. She claimed to have a very high recovery rate but published no clinical data to substantiate this. Scientists who attempted to isolate the organism she postulated found that it was a common skin bacterium. Researchers at the University of Pennsylvania Cancer Center compared 78 of its patients with similar patients treated at the Livingston-Wheeler Clinic. All had advanced cancers for which no proven treatment was known. As expected, the study found no difference in average survival time of the two groups. However, Livingston-Wheeler patients reported more appetite difficulties and pain *(27)*.

Mental Imagery

Mental imagery involves the use of detailed mental images in an attempt to control a situation. For example, cancer patients may imagine that their white blood cells are little knights in white armor attacking their tumors, which they picture as black dragons. Imaging may have some usefulness as a relaxation technique in dealing with tension or chronic pain, but

there is no scientific evidence that it can influence the course of any organic disease.

O. Carl Simonton, MD, claims that cancers can be affected by relaxation and visualization techniques. He claims that this approach can lessen fears and tension, strengthen the patient's will to live, increase optimism, and alter the course of a malignancy by strengthening the immune system. However, he has not published the results of any well-designed study testing his ideas. Simonton theorizes that the brain can stimulate endocrine glands to inspire the immune system to attack cancer cells. Toward this end, he has advised cancer patients to imagine their cancer being destroyed by their white blood cells. However, there is no scientific evidence that white cells actually attack cancer cells in this manner or that "immune suppression" is a factor in the development of common cancers.

Bernie Siegel, MD, author of *Love, Medicine & Miracles and Peace, Love & Healing,* claims that "happy people generally don't get sick" and that "one's attitude toward oneself is the single most important factor in healing or staying well." Siegel states that "a vigorous immune system can overcome cancer if it is not interfered with, and emotional growth toward greater self-acceptance and fulfillment helps keep the immune system strong." His Exceptional Cancer Patients program includes weekly peer support and family therapy, individual counseling, and the use of positive imagery. Siegel's claims are not supported by scientific studies. A 10-year study found that 34 breast cancer patients participating in his program did not live longer after diagnosis than comparable nonparticipants *(28)*.

"Metabolic Therapy"

Proponents of "metabolic therapy" claim to diagnose abnormalities at the cellular level and correct them by normalizing the patient's metabolism. They characterize cancer, arthritis, multiple sclerosis, and other "degenerative" diseases as the result of metabolic imbalance caused by a buildup of "toxic substances"

in the body. They claim that scientific practitioners merely treat the symptoms of the disease, whereas they treat the cause by removing "toxins" and strengthening the immune system so the body can heal itself. The "toxins" are neither defined nor objectively measurable. "Metabolic" treatment regimens vary from practitioner to practitioner and may include a "natural food" diet, coffee enemas, vitamins, minerals, glandulars, enzymes, laetrile, and various other nostrums that are not legally marketable in the United States. No scientific study has ever shown that "metabolic therapy" or any of its components is effective against cancer or any other serious disease.

Pau D'Arco Tea

This tea, sold through health food stores and by mail, is also called taheebo, lapacho, ipe roxo, or ipes. The tea is claimed to be an ancient Inca Indian remedy prepared from the inner bark of various species of *Tabebuia,* an evergreen tree native to the West Indies and Central and South America. Proponents claim that pau d'arco tea is effective against cancer and many other ailments. *Tabebuia* woods contains lapachol, which has been demonstrated to have antitumor activity in a few animal-tumor models. However, no published study has shown a significant effect on cancer in humans. Studies during the early 1970s found that low doses of lapachol can cause nausea and vomiting and can interfere with blood clotting.

Revici Cancer Control

Also called lipid therapy and "biologically guided chemotherapy," Revici cancer control is based on the notion that cancer is caused by an imbalance between constructive ("anabolic") and destructive ("catabolic") body processes. Its main proponent, Emanuel Revici, MD, prescribed lipid alcohols, zinc, iron, and caffeine, which he classified as anabolic, and fatty acids, sulfur, selenium, and magnesium, which he classified as catabolic. His formulations were based on his interpretation of the specific gravity, pH (acidity), and surface tension of single samples of the

patient's urine. Scientists who have offered to evaluate Revici's methods were unable to reach an agreement with him on procedures to ensure a valid test. However, his method of urinary interpretation is obviously not valid. The specific gravity of urine reflects the concentration of dissolved substances and depends largely on the amount of fluid a person consumes. The acidity depends mainly on diet, but varies considerably throughout the day. Thus, even when these values are useful for a metabolic determination, information from a single urine sample would be meaningless. The surface tension of urine has no medically recognized diagnostic value. Recently, following a lengthy struggle with New York State licensing authorities, Revici's medical license was permanently revoked.

Shark Cartilage

Powdered shark cartilage is purported to contain a protein that inhibits the growth of new blood vessels needed for the spread of cancer. Although a modest anti-angiogenic effect has been observed in laboratory experiments, it has not been demonstrated that feeding shark cartilage to humans significantly inhibits angiogenesis in patients with cancer. Even if direct applications were effective, oral administration would not work because the protein would be digested rather than absorbed intact into the body.

Nevertheless, in the spring of 1993, "60 Minutes" aired a program promoting the claims of biochemist/entrepreneur I. William Lane, PhD, author of the book *Sharks Don't Get Cancer*. The program highlighted a Cuban study of 29 "terminal" cancer patients who received shark-cartilage preparations. Narrator Mike Wallace filmed several of the patients doing exercise and reported that most of them felt better several weeks after the treatment had begun. The fact that "feeling better" does not indicate whether a cancer treatment is effective was not mentioned. Nor was the fact that sharks do get cancer, even of their cartilage. NCI officials subsequently reviewed the Cuban data and con-

cluded that they were "incomplete and unimpressive." A well-designed clinical trial involving 58 patients subsequently found no benefit *(29)*.

Vitamin C

The claim that vitamin C is useful for treating cancer is largely attributable to Linus Pauling, PhD. During the mid-1970s, Pauling began claiming that high doses of vitamin C are effective in preventing and curing cancer. In 1976 and 1978, he and a Scottish physician, Ewan Cameron, reported that a group of 100 terminal cancer patients treated with 10,000 mg of vitamin C daily had survived three to four times longer than historically matched patients who did not receive vitamin C supplements. However, Dr. William DeWys, chief of clinical investigations at the NCI, found that the patient groups were not comparable. The vitamin C patients were Cameron's, while the other patients were managed by other physicians. Cameron's patients were started on vitamin C when he labeled them "untreatable" by other methods, and their subsequent survival was compared to the survival of the "control" patients after they were labeled untreatable by their doctors. DeWys found that Cameron's patients were labeled untreatable much earlier in the course of their disease—which meant that they entered the hospital before they were as sick as the other doctors' patients and would naturally be expected to live longer *(30)*. Nevertheless, to test whether Pauling might be correct, the Mayo Clinic conducted three double-blind studies involving a total of 367 patients with advanced cancer. All three studies found that patients given 10 g of vitamin C daily did no better than those given a placebo.

Some Final Thoughts

"Alternative medicine" has become the politically correct term for questionable practices formerly labeled quack and fraudulent. The science-based medical community is committed to

testing its theories and practices and developing a coherent body of knowledge. The "alternative" community is not. The scientific community is willing to examine new ideas but gives priority to those that appear most promising. However, this openmindedness of science is not emptyheadedness. Enough is known to conclude that many "alternative" practices are worthless.

Reliable Information Sources

• The National Council Against Health Fraud serves as a clearinghouse for information on health frauds, quackery, and "alternative" methods. It publishes position papers, fact sheets, a bimonthly newsletter, and a recommended reading list. Information can be obtained by writing to P.O. 1276, Loma Linda, CA 92354; calling (919) 824-4690; or visiting its web site: http://www.ncahf.org.

• The Committee for the Scientific Investigation of Claims of the Paranormal (CSICOP) investigates paranormal and fringe-science claims. It publishes a bimonthly magazine, *The Skeptical Inquirer,* and maintains subcommittees on paranormal health claims and several other topics. Its address is PO Box 703, Buffalo, NY 14226.

• The Consumer Health Information Research Institute (CHIRI) promotes consumer and patient education activities, including studies of misinformation, fraud, and quackery. Individual consultations are available by calling (816) 228-4595.

• The National Association for Chiropractic Medicine (NACM) is composed of chiropractors who shun unscientific methods and limit their practice to conservative treatment of musculoskeletal disorders. Its referral list can be accessed by sending a self-addressed, stamped envelope to 15427 Baybrook Street, Houston, TX 77062.

• The American Cancer Society (800) 227-2345 or a local office) can supply position papers on many questionable methods.

Recommended Books

• Barrett, S. et al. (1997). *Consumer Health: A Guide to Intelligent Decisions,* 6th Edition, Brown & Benchmark, Madison, Wis.

• Barrett, S. and Jarvis, W. T. (eds.) (1993) *The Health Robbers: A Close Look at Quackery in America.* Prometheus Books, Amherst, N.Y.

• Barrett, S. and Herbert, V. (1994) *The Vitamin Pushers: How the "Health Food" Industry Is Selling America a Bill of Goods.* Prometheus Books, Amherst, N.Y.

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Abstract

Progress in the last 100 years or so in the field of medicine has served us well, particularly in the treatment of communicable diseases, trauma, and surgically correctable conditions. However, the current healthcare system has become extremely technocratic, depersonalizing, expensive and unable to deal with the chronic disease crisis the United States is facing. The hundreds of billions of dollars poured into the biomedical model-based research in the hope of finding "magic bullet" solutions has been largely unsuccessful, but the system still continues to invest billions in the model.

The report, "Healthy People 2000" by the US Department of Health and Human Services recommends the need to completely revamp the current approaches to healthcare. It enumerated the challenges and goals for improving the nation's collective health by concluding that health of people is measured by more than death rates. It comes from improved quality of life and reducing suffering, illness, and disability. It calls for investigating "alternatives" to current "disease care" approaches.

Complementary and alternative medicine (CAM) modalities, largely derived from early systems of medicine, with their emphasis on mind–body–consciousness approaches to healthcare, may serve us well as a starting point of the revamping process. A large percentage of the US population, frustrated with the ineffectiveness of the biomedical model-based healthcare system to take care of their problems of chronic

diseases in a humane way, is using CAM modalities with or without conventional therapies. Healthcare economics, public demand, and political recognition of CAM modalities are forcing the medical establishment, the hospitals, healthcare-maintenance organizations, and medical- educational institutions to relax their stand against the use of CAM modalities.

Understanding the Integration of Alternative Modalities into an Emerging Healthcare Model in the United States

Vimal Patel, Ph.D.

Introduction

Over three centuries of a one-pointedness approach to medicine based on the Cartesian/Newtonian biomechanical model has resulted in unparalleled advancement of physical medicine known to humankind. The field of modern allopathic medicine certainly can claim that the one-pointedness approach has produced healthier human societies than previously known to us, especially in terms of communicable diseases, emergency medicine, and other structural abnormalities correctable by surgical intervention.

The obvious success of the modern "high-tech" medicine in the communicable and acute-care areas has given us a false

sense of confidence, particularly in our medical-research establishment, educaton system, and healthcare industry, that the technological development will provide answers to all our society's healthcare needs. As a result, the medical-education system and healthcare industry have mainly focused their energies on "disease care" rather than "health care." Moreover, the success in the abovementioned areas and the societal overdependence on the conventional "high-tech" medicine has made the disease care system the only politically acceptable healthcare system. This has allowed the system to enjoy essentially total control of the healthcare policies and medical educational, informational, and research resources of the nation. Having obtained the political control of the healthcare system, the medical establishment has little difficulty in preventing integration of potentially cost-effective unconventional therapies and practices into the evolving healthcare system by labeling them as "unproven, disproven, controversial, fradulent, unscientific, and/or questionable" without a fair trial *(1–3)*. Since the Congress of the United States in 1991 mandated the creation of Office of Alternative Medicine (OAM) at the National Institute of Health (NIH) to "more adequately explore unconventional medical practices," the alternative therapies and practices have been getting deserving attention of public, news media, healthcare writers, and healthcare professionals of this country.

The narrowly defined biomechanical healthcare model treats the human body as a machine and thus has necessarily allowed negligence of mental and spiritual aspects of human health. In fact, the methodologies of the allopathic system of medicine have been developed to preclude the role of mental and spiritual spheres in human health and existence. The ever-increasing and unaffordable healthcare costs of high-tech medicine, chronic disease crisis, and ineffectiveness of the allopathic healthcare model to deal with people suffering from chronic illness in a humane way has called into

question the very foundation of the mainstream healthcare system in this country.

Although the medical establishment has been slow in recognizing the role of mental and spiritual aspects of human beings in health, a significant number of people and healthcare professionals of this country do recognize their role in health. Many complementary and alternative medicine (CAM) therapies and practices with their roots in ancient medical systems of both the East and the West that recognize the role of mind and spirit in human health have gained increasing popularity in this country for the last two to three decades. In fact, according to a recent survey *(4)* one in three Americans regularly incorporate CAM therapies/practices into their healthcare need and most of whom, for the fear of being ridiculed, do not discuss these therapies with their allopathic physicians.

People in the United States have already taken the lead in integrating CAM therapies and practices into their healthcare and medical establishments may simply have to follow the lead. Integrating body–mind–spirit approaches into the existing healthcare model is not an option but a necessity for creating a healthy and responsible society. Integrating CAM approaches into the conventional healthcare model necessarily will require careful evaluation of these therapies and practices with methodologies that include mental and spiritual aspects of human beings.

What Is CAM?

Along with the allopathic Western medicine, there are now a great number and variety of systems of health belief and practices in the United States, with its large immigration population. The technological advancement in the field of the dominant allopathic system of medicine has not affected the popularity of the nonbiomedical therapies and practices. In fact, they are growing in popularity *(4)*. Included among these are long-standing traditional systems, such

as Ayurveda, traditional Chinese medicine, Native American medicine, homeopathy, and others, often called "folk medicine," and newer developments grouped as "holistic health" or "New Age" healing. Collectively these nonbiomedical systems, therapies, and practices have been referred to as CAM by the recently created OAM.

The CAM modalities are generally considered to be lacking sufficient documentation for safety and effectiveness against specific diseases and conditions in the United States, are not taught in US allopathic medical schools, and are not practiced in US hospitals. Also, CAM services are not reimbursed by healthcare insurance providers. However, the aforementioned outlook about CAM modalities is changing rapidly in that many well known medical schools are teaching some aspects of CAM, hospitals are incorporating some of the CAM therapies, and some healthcare insurance providers are reimbursing some CAM modalities.

There are over 200 CAM modalities. Because of the wide variety of medical systems, therapies, and practices that the term CAM includes, they cannot easily be categorized. As pointed out by Dossey and Swyers *(5),* despite this diversity, most CAM modalities do hold some common beliefs. These include:

1. That healing is innate to the human body and therapies/practices can stimulate the natural healing processes;
2. That the individual represents a microcosm of the societal reality, and that one's relationships and place in society, and one's sense of value and self-esteem affects one's health,
3. That religious and spiritual values are an important part in health;
4. That consciousness is the underlying principle for manifestation of life; that is, one's thoughts, attitudes, feelings, emotions, values, and perceived meanings are capable of directly affecting one's physical function; and
5. That all aspects of the individual–physical, emotional, mental, psychosocial, diet, and lifestyle—are interrelated and must be considered in treatment.

The integrated approach is aimed at restoring the balance among organs in the body, body systems, person's diet, relationship with others in society, and with nature. As CAM practitioners often measure their treatment success or lack of it on healing the whole person rather than just focusing on curing a given condition/disease, it is possible in this view for the person to be healed without the disease being cured.

A glossary of some of the commonly available CAM systems, techniques, and practices in the United States is given in the Appendix. These modalities can be broadly classified into three areas; namely physical therapies, such as the Alexander technique, chiropractic, applied kinesiology, yoga therapy, and so forth; energy therapies, such as acupuncture, bioenergetic Chi Gong, pranayama, therapeutic touch, and so on; and systems and therapies not covered by physical and energy therapies, such as Ayurveda, Chinese tradiotional medicine, homeopathy, naturopathic medicine, and others.

Prevalence and Distribution of CAM

Today millions of Americans, especially the better-educated, spend billions of dollars every year on various CAM therapies and practices, such as herbs, acupuncture, meditation, and yoga, among others. A number of studies since the mid-1970s have shown widespread use of CAM *(4, 6–9)*. In fact, between 70 and 90% of the world's population rely on so-called CAM as their primary form of healthcare *(10,11)*. Contrary to conventional wisdom, the use of CAM modalities is not confined to "marginal" groups. It is fairly well established that many ordinary individuals' healthcare strategies often involve the use of both biomedical and CAM approaches in varying combinations. In fact, in 1990 Americans made more total visits to practitioners of CAM than to all the primary care allopathic physicians—425 million visits vs 388 million vis-

its—and most of these visits to CAM practitioners were paid out of pocket. Americans spent nearly $14 billion dollars on CAM therapies *(4)*. This out of pocket expenditure ($13.7 billion) exceeds the out-of-pocket expenditure for all hospital care in the United States that year ($12.8 billion). Furthermore, as the survey *(4)* indicates, the majority of the people seeking CAM therapies are those with chronic illness who believe that conventional medicine has few, if any effective treatment for their condition.

As pointed out by David Hufford *(12)* in large part, prevalence and distribution of CAM will determine the success or failure in establishing knowledge claims, which in turn affects the allocation of resources and authority. The most technically perfect experiments and theories have little importance unless they are accepted by relevant sectors of society. The prevalence and distribution of beliefs and practices dissenting from official views are especially important because consensus determines what is official. Consensus among a powerful minority can have great influence on official views, but power and the prevalence of views within a population interact in determining what can be maintained as official. This is the political dimension of knowledge-making. In a democracy especially, the ability of an elite minority to retain the privilege of establishing official views depends on the extent and solidarity of opposing, unofficial views. For that reason, the prevalence and distribution of CAM has been a topic of cultural battles throughout the brief history of conventional medicine.

The appropriation of $2 million dollars for the establishment of the OAM in 1992 represented a shift from determining programs of the NIH exclusively by the prevalence and distribution of ideas among biomedical scientists to giving weight to the prevalence and distribution of ideas in the general population. The OAM has been charged with the mission of identifying and evaluating unconventional healthcare practices and therapies that maintain or induce healing processes that, in turn, promote wellness and alleviate

suffering, illness, and disease. The office supports and conducts research and research training on these practices and therapies and disseminates the information on their clinical usefulness, scientific validity and theoretical underpinnings.

Forces Driving the Increased Use of CAM

Freedom of Healthcare Choices

Benjamin Rush, M.D., Signer of the Declaration of Independence, Physician to George Washington, speaking about freedom of choices once said, "The constitution of this Republic should make special provision for Medical Freedom as well as Religious Freedom... To restrict the art of healing to one class of men and deny equal privileges to others will constitute the Bastille of medical science. All such laws are un-American and despotic. They are fragments of monarchy and have no place in a Republic." Even today the issue is being debated.

Medical freedom in the United States until the mid-1800s was a reality, as evident by the competition among various medical practitioners of the time, such as homeopaths, naturopaths, botanics, and Thomsonians *(13)*. Two important observations made in the early 1800s: specific organic entities—bacteria—were responsible for producing particular disease states and characteristic pathological damage; and certain substances—antitoxins and vaccines—could improve a person's ability to ward off the effect of these and other pathogens. As a result of these discoveries, the era of "biomedicine," the dominant medical system of today, began.

Endowed with this knowledge, researchers and clinicians began to conquer a variety of devastating infectious diseases and perfect surgical procedures. As their success increased, biomedical scientists began to believe that once they found the offending pathogen, metabolic error, or chemical imbalance, all illnesses, including mental illnesses, would yield to appropriate vaccine,

antibiotic or chemical drug *(14)*. This philosophy led them to extend their purview beyond the areas of physical and mental diseases. Births and deaths, which traditionally had taken place at home and were part of the religious domain, now were moved to the hospital, the biomedical domain.

The formation of the American Medical Association (AMA) in 1847, the establishment of the Pure Food and Drug Act of 1906, and Flexner's report on Medical Education in the United States and Canada of 1910 had essentially sealed the fate of competing non-biomedical forms of medicine *(15,16)*. By the early part of this century, biomedicine had become the convention for every facet of illness and health. For the next five decades, the biomedical model of healthcare overshadowed any other model and those who adopted and practiced biomedicine gained economic, social, and political prestige and power. Rival healing professions and perspectives gradually disappeared and/or were relegated to "fringe" status, or were swallowed up by the biomedical paradigm. Also, some nonbiomedical medicine degenerated into stereotypical "snake oil" proprietary medicines, thus further eroding the credibility of legitimate alternative medicine practitioners.

However, in the last three to four decades reports have emerged on the side effects and inadequacies of widely used drugs, and new strains of microbes appeared that were resistant to the first magic bullet, antibiotics. The use of new and more powerful antibiotics also began to become ineffective as resistant strains of bacteria evolved. Furthermore, the biomedical model essentially failed to find cures for chronic diseases, such as allergies, arthritis, depression, hypertension, cardiovascular diseases, digestive problems, diabetes, obesity, and so forth, which had replaced infectious diseases as the major killers and cripplers of the American population. These developments have shaken the consumer confidence in the conventional medicine. These consumers are increasingly exploring the availability of CAM choices for their healthcare.

Inconsistency of Cartesian/Newtonian Biomedical Model with Human Experience and Emerging Science

The current medical model is guided by the classical laws of matter and energy that Isaac Newton described in the 17th century. According to these laws, the entire universe, including the body, is a vast clockwork that functions with deterministic causal principles. If they are to be effective, all forms of therapy must embody this physicalistic assumption. This medical model assumed that the effect of the mind and consciousness were of secondary, if of any importance at all. This narrowly defined conceptual framework of *conventional medicine* has restricted the growth in the understanding of the role of the Body–Mind–Spi·it complex in human health and is inconsistent with the emerging field of psychoneuroimmunology *(17)*.

One of the most accurate and verifiable sciences, modern physics, has found that the Newtonian concept of independence of observer, process of observation, and the observable is not valid. The observer is an integral part of the process of observation and observable. Thus, according to the quantum theory and Einstein's theory of relativity, the observations can only be expressed as correlations rather than simple causes and effects.

In quantum physics, the nonlocal interactions between particles (the so-called Einstein-Podolsky-Rosen paradox), which cannot be connected by signals moving even with the velocity of light have been predicted and verified *(18)*. The quantum theory has been verified to be highly accurate and so far, no contradiction has been found from the prediction of the quantum theory. The latest achievement is the demonstration of the Bose-Einstein condensate (predicted over 70 years ago) representing several thousand atoms in a state of maximum coherence with one wave function. The achievement of the new state of matter *(19)* was declared by *Science* as the 1995 molecule of the year *(20)*. No such state is possible in the *Newtonian model*. Quantum effects on a large scale have been manifested in the phenomena of super-

fluidity, super-conductivity at temperatures much higher than absolute zero. Other examples of quantum effects on a large scale are observed in semiconductors, transistors, tunnel diodes, laser beams, etc.

In general, the quantum effects are observed when there is maximum atomic and/or molecular coherence. These states are observed in conditions of the least molecular, atomic or particle agitation. The behavior of these quantum states are non-Newtonian and apparently anti-intuitive. It is highly probable that the mind–body consciousness interactions occur at quantum levels and therefore can only be expressed as correlations. The physicist theory of Neil Bohr suggests that matter and mind (consciousness) are complementary in the sense that they are two contradictory sides of the same reality. The original Bohrean complimentarity was physical; the union of such opposites as wave and particle in the nature of an elementary piece of matter, for instance, an electron or a proton. The "inherent ability" of subatomic particles to have such opposite properties as wave and particle perhaps represents the consciousness component of matter.

> In the words of George Wald, winner of the 1967 Nobel prize for physiology or medicine, objection will be raised by those who want to insist that a material universe is all the reality there is. Materialism of this kind is a doctrine that anyone may choose as a working hypothesis or as a religion, but I am unaware of a proof of it. On the contrary, the scientific method, which was designed on a basis of materialism in a deliberate attempt to exclude nonmaterial considerations, has led to other prominent scientists from Newton and Galileo on down to conclude that there were problems rooted in science but unassimable as science *(21)*.

If such questions arose in the days of absolute, classical science, how much more likely are they today in the era of quantum and relativity theories, when reality is no longer something separate from us to be contemplated externally, but an experi-

ence in which the observer is always necessarily involved. It has been proven by modern physics that every measurement disturbs the thing that is measured. Perhaps what we need is a kind of *Bohrean* complementarity of method, in which all of the methods that humanity has historically used to approach reality—scientific, philosophical, theological, esthetic, and mystical—are used together in all of their vigor. Such a procedure would require minds willing to tolerate, or even enjoy, paradox, contradiction and antinomy.

Complementary and alternative medicine systems of early years, whether Indian, Chinese, Greek, Islamic, or Native America, recognized the role of consciousness in human health. As an example, the Ayurveda, the millennia-old system of medicine from India, states that

> human health is a product of interaction and interconnectedness of physical, mental and spiritual spheres both at cosmic and individual levels and that the underlying principle is spiritual sphere for the existence of physical and mental spheres. The modern field of psychoneuroimmunology clearly indicates the role of emotions, thoughts or mind on the immune functions, and thus health *(17)*.

One of the theoretical basis of the Ayurvedic system of medicine is Patanjali's Yoga. The Science of Yoga deals with producing higher states of consciousness that is different from waking, dreaming, and sleeping states. The process of achieving these states has been experimented for thousands of years by many cultures. As the quantum state of matter is achieved by reducing the thermal agitation to its lowest level, likewise the higher states of consciousness are achieved by reducing the sensory inputs to their lowest possible levels, thereby producing the awareness without a thought and outside the parameters of space and time.

Transcendental Meditation (TM) of Maharishi Mahesh Yogi, derived from Patanjali's Yoga, is one of the most scientifically

investigated techniques and has been shown to produce states that are physiologically different from waking, dreaming, and sleeping *(22)*. The TM state is characterized by quiescence of the sympathetic nervous system *(23)*. Daily experience of the TM state for short durations (20–40 minutes) has been shown to improve development of mental potential, health, social behavior, and quality of life *(24)*.

Increasing Healthcare Cost Providing Less

In 1940 *(25)*, the United States spent $4 billion a year, a mere 4% of the country's gross national product (GNP). Today, because of increasing sophistication of the US healthcare system, its increasing administrative costs, and the expanding degree of training and specialization required by the healthcare practitioners who administer it, we spend an estimated $4 billion every day; that is, over $1.4 trillion or over 15% of the GNP. The bio-medical model of healthcare with its emphasis on intervention rather than prevention, has generated a crisis of healthcare of epic proportions. People are frustrated and dissatisfied with the United States' current healthcare system. Doctors and patients alike feel depersonalized and used. The Unites States spends far more money for healthcare than any other nation in the world and it is the only nation in the industrialized Western world that does not guarantee minimum healthcare to every single citizen. Over 40 million Americans under the age of 65 are uninsured and another 29 million underinsured. Approximately 70 million people, one-third of the US population under the age of 65, may be unable to afford healthcare despite federal and state efforts to expand medical coverage *(26)*. The "sophisticated" medical healthcare system of the United States does not perform as well as the Chinese "primitive" healthcare system in terms of two important healthcare measures—namely infant mortality and life expectancy at birth. For example, in New York City, the infant mortality rate is 10.8 per 1000 births, while in Shanghai, China, the rate is 9.9. Life expectancy in New York City for whites is 73

and for people of color it is 70. In Shanghai, however, the life expectancy is 75.5 years. Shanghai is an extremely overcrowded and polluted Third World city in a country with a per capita income of only $350. Shanghai spends just $38 per person annually on medical care compared to New York City's $3000, yet generates a better health record than New York, perhaps because of its preventive and caring healthcare and lifestyle *(27,28)*.

If recently proposed Congressional changes in Medicaid are enacted, and with managed care thriving and tightening its hold on the well-insured population, negotiated discounts and stricter financial contracts will make it increasingly difficult to subsidize care for the underinsured. As a result, the uninsured and underinsured are likely to be at severe risk for new access barriers and diminished care. Understanding the risk and implication of managed care and absent universal coverage is one of the central public policy concerns for the approaching 21st century.

Chronic Disease Crises

Today, almost 38 million Americans are functionally limited in their daily activities owing to chronic, debilitating conditions, such as arthritis, allergies, pain, hypertension, cancer, depression, cardiovascular disease, and digestive problems. It is estimated that over 70% of the current healthcare budget is spent on the treatment of these individuals; such conditions will continue to consume an even larger proportion of the national healthcare expenditure as the population grows older. Additionally, the worldwide pandemic of AIDS is threatening to completely overwhelm the healthcare delivery system in certain areas of the United States *(29)*.

Whereas the dominant system of healthcare in the United states—often called conventional medicine or medicine based on the biomedical model—is extremely effective for treating infectious diseases, traumatic injuries, and other acute situations, it is often ill-equipped to handle complex, multifaceted, chronic conditions. One reason is that over the years, conventional medicine

has increasingly emphasized finding a single magic bullet solution for each condition or disease it confronts.

The reality is that many chronic conditions are not amenable to such one-dimensional solutions. For example, for decades the leading causes of death in the United States have been and continue to be heart disease and cancer. Spending hundreds of billions of research dollars in the hope of finding causes and cures for heart disease and cancer based on magic bullet or biomedical approaches has certainly increased our awareness concerning the mechanisms of these diseases, but not much about the hope of the magic bullet cure. In fact, the death and disability rate from these chronic conditions continues to be the same or even increasing, particularly for cancer *(30,31)*. In general, the advance in biomedical science has essentially failed to alter the course of the chronic diseases, the major factor for rising healthcare costs. It is in this area of healthcare, where the majority of US healthcare dollars are spent, that CAM modalities, with their mind–body–spirit approaches, appear to be cost-effective and promising. This is particularly true for the cardiovascular diseases and cancers, two of the leading causes of cripplers and deaths in the United States *(32,33)*. For example, an account of cost-effective comprehensive nutritional, lifestyle changes, stress reduction, and support–group alternatives to surgery and drugs for cardiovascular diseases can be found in books by cardiologists Dean Ornish, *Reversing Heart Disease* and Stephen Sinatra, *Healing the Secret Causes of Heart Disease (34,35)*. In his recently released book, John Robbins has given an excellent account on the pitfalls of expensive and ineffectiveness of standard cancer therapies along with alternative therapies that have worked but have not been accepted by the medical establishment *(33)*.

Criteria For Integrating CAM

For several millennia, healers and health practitioners of the world have played their part in building up the body of medical

knowledge that we now possess. Many CAM modalities have their roots in an early medical system, whether Native American, Indian, Chinese, Islamic, or Greek. Early medicine was concerned with ways of keeping the individual healthy and healing the sick. Because the mechanism of many diseases was poorly understood in those days, these systems have developed many functionally effective ways to enhance the host's defensive mechanisms to counter and/or treat illnesses. However, these systems were naturally weak in dealing with infectious diseases and surgically correctable conditions.

During the last 100 years—the era of the biomedical system's growth—we have seen that the vaccine and antibiotics can prevent and conquer once-deadly infections, such as smallpox, polio, meningitis, rheumatic fever and other childhood diseases. Surgery and chemotherapy have removed and shrunk some tumors. Biomedical scientists have isolated and synthesized the insulin that enables some diabetics to live long and productive lives. Surgical advancement in organ-transplant procedures has given a new lease on life to many individuals with failing organs. Premature infants, who would never have survived before, have lived. And now, the inherited diseases that were thought just a few years ago to be beyond therapeutic reach may be treated by genetic-splicing procedures. These kinds of successes, though in a limited area of medicine, namely drugs and procedures, has created indomitable hope on the part of many biomedical professionals that all illnesses might eventually yield to their relentless research efforts.

Healthcare delivery apparatus, i.e., the hospitals of the medical establishment, in response to economic forces driven by consumer demand, have begun to incorporate some of the mind–body–consciousness-based approaches, and are beginning to create the database for validating the clinical usefulness of the new approaches. This is unusual, as the hospitals previously had followed the "norms" developed by the research and educational arms of the establishment. This has been the case, becuase the

research and educational arms of the "biomedical model"-based medical establishment have been insulated by the unquestioned support of both the local and federal governments and healthcare industries. As a result, the biomedical research and educational establishment has not paid any attention to either developing methods that would address the evaluation of the mind–body–consciousness approaches or evaluate them with many good available methods. It has been easy to discard these potentially cost-effective approaches by labeling them "unproven," "unscientific," "non-scientific," "questionable," etc., because they were not investigated by the so-called randomized double-blind controlled trials (RCT), the "gold standard" for clinical evaluations. However, the establishment has no problem accepting more than three-quarters of all the medical procedures and drugs that have been handed down without the RCT. Many of the CAM approaches have been in use for millennia in other cultures and may be a good starting point in dealing with the chronic disease crisis faced by the US healthcare system. Certainly these approaches need to be investigated, however, the RCT is not the method of choice for these comprehensive healthcare modalities *(36,37)*. In fact, the RCT should be questioned for evaluation of the pure pharmaceutical compounds as well *(38)*.

Historically, Americans have wanted innovations and progress, but the medical establishment, working with a narrowly defined "scientific model," is willing to ignore the ineffectiveness and failures of drugs and procedure approaches in dealing with chronic illnesses, which consume most of our ever increasing healthcare dollars. For example, chemotherapy turned out to be less successful in treating cancer than we had hoped for, angioplasty, bypass surgery and anti-inflammatory drugs address symptoms, not causes, yet we continue to invest billions in them and keep on hoping. The time has come to admit the limitations of the "biomedical model" and invest in investigation and integration of "mind–body–spirit" approaches of long-standing tra-

ditional and newer CAM modalities in our emerging healthcare model. An effective healthcare model should:

1. Be based on sound scientific principles;
2. Accommodate evolving science and technology;
3. Be compatible with the conventional medical system;
4. Recognize the uniqueness of each individual;
5. Promote a disease preventing healthy lifestyle;
6. Provide cost-effective treatments; and
7. Acknowledge the holistic nature of health (that is, physician, patient, and intervention as equal partners in the healing process).

Ayurveda as Prototype for an Emerging Healthcare Model

The criteria set in the previous section for the emerging healthcare model in the United States are found in the millennia-old system of medicine from India called Ayurveda, or science of life. The lessons of the system could serve as a prototype for the emerging healthcare system.

The Ayurvedic system of medicine is based on the *shamkhya* and *Yoga* hypothesis of Kapila and Pantajali *(39,40)*. These hypotheses are analogous to the Quantum theory and Einstein's theory of relativity, which provide the verifiable prediction for the behavior of energy and matter. The most fundamental outcome of these theories is that the observer, the process of observation, and the observed are interdependent and inseparable. In other words, observations can only be expressed as correlations instead of simple causes and effects.

The *shamkhya,* or numerical representation of the cosmos, provides the theoretical or philosophical basis of life's goal, and *Yoga* provides the techniques to achieve the goal of life. The goal of life is to recognize the fact that individual existence is a microcosm (Fig. 1) of cosmic reality and that to be healthy,

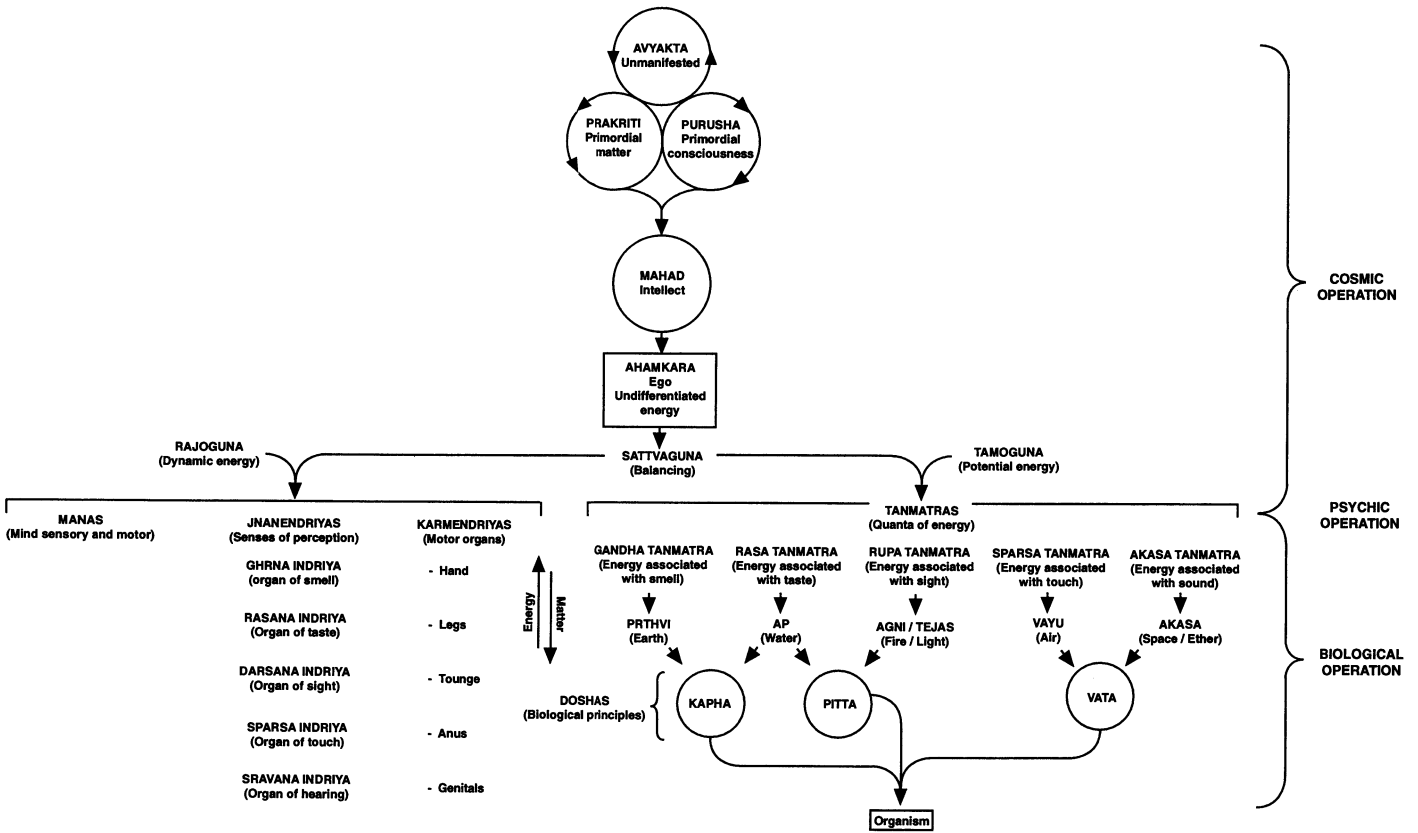

Fig. 1. Evolution of Tridosha: The Foundation of Ancient Medical System of India (Ayurveda/Siddha).

the life has to be lived within the cosmic rhythm. The *Yoga* provides the verifiable steps to achieve the ultimate goal of the life. These steps are an integral part of the Ayurvedic system of medicine.

According to the Ayurvedic hypothesis, human health is a product of the interaction and interconnectedness of the physical, mental, and spiritual spheres both on the cosmic and the individual levels, and the spiritual (consciousness) sphere is the underlying principle for the existence of the physical and mental spheres. The fundamental outcome of the Ayurvedic hypothesis is that human health and behavior reflect the integration of these three spheres. In other words, optimum integration generates optimum health and behavior.

The Ayurvedic system essentially deals with enhancing the integrative process among these three spheres. It has developed simple, effective, and personalized ways to harmonize and balance these spheres to maximize the individual's health. For disease prevention, Ayurveda prescribes routines for when to sleep and wake; how to breathe; what to eat; how to prepare and eat food; when, how, and what to drink; how, when, and what to see, hear, touch, taste, etc., based on one's basic constitution. It also provides detailed guidance for nutrition based on not only caloric, vitamin, and mineral content, but also on taste and subtle effects of a given food on a given individual. It provides special physical exercises called asanas for maintaining balanced musculature. There are specific techniques, such as pranayama or special breathing, meditation, mental visualization, contemplation, and so forth, to reduce mental agitation. Ayurveda also includes many other routine and specific therapies, such as sound therapy, aromatherapy, color therapy and massage therapy to harmonize and balance the sensory inputs. Panchkarma, or five action therapies, are used to remove toxins from mind and body. All of these therapies are designed to restore the balance among the physical, mental and spiritual spheres.

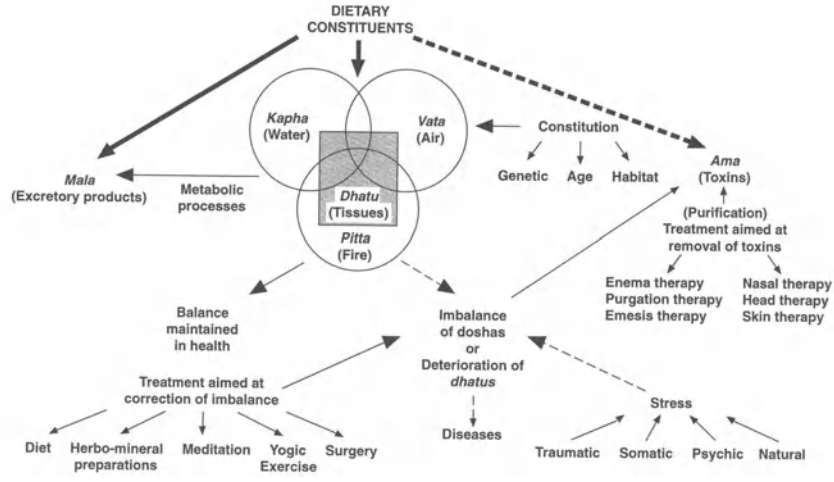

Fig. 2. Origin of diseases and principles of treatment in Ayurveda/Siddha.

Ayurvedic materia medica include more than 8000 preparations derived from plants, dairy products, and minerals to enhance the body's defensive mechanisms. Surgery and psychiatric therapies are also an integral part of Ayurveda. The Ayurvedic physician primarily identifies the deviation(s) in natural rhythm of a patient based on the patient's individual constitution and then treats and guides the patient to restore the rhythm and balance as outlined in Fig. 2.

The strong points of the Ayurvedic system are a sound scientific base, emphasis on nutrition and selfcare, routines for disease prevention, therapies for chronic conditions, simplicity, cost-effectiveness, and an integrated approach to health and disease. Although there is a need for more research with modern scientific methodology, the available clinical and basic research evidence *(41–47)* supports Ayurveda's scientific validity and clinical usefulness. The lessons of Ayurveda could serve as well in the development of an emerging healthcare model in this country. Ornish's program for reversing heart disease without drugs or surgery which uses diet, meditation, exer-

cise, and support groups represents in large part the components of the Ayurvedic medicine.

Medical Establishment and CAM

Many physicians, nurses, medical educators, and scientists have recognized the limitation of the current healthcare system based on the biomedical model and have been sympathetic toward the CAM modalities. However, those who have adopted CAM modalities in their practices have been heavily punished by the establishment, state Medical Boards, AMA, or FDA *(48)*. When it comes to treating patients, the AMA, the most powerful arm of the establishment, has never permitted CAM alternatives to drugs and surgery. In fact, the AMA has actively opposed any possible competition from "non-biomedical" fields. In its early history, the AMA succeeded in opposing and eventually eliminating the homeopathic and other competing medical practices *(48–50)*. The establishment also used similar tactics to eliminate competition from midwives *(49)*. In 1963, the AMA formed a committee called, "Committee on Quackery" with an aim to undermine or eliminate holistic healing practices, particularly chiropractic practice. Various tactics employed by the establishment to eliminate chiropractic medicine failed and the entire campaign blew up in the AMA's face. On August 24, 1987, US District Court Judge Susan Getzendanner ruled that the AMA and its officials were guilty of attempting to eliminate the chiropractic profession. This conduct, she said, "constituted a conspiracy among the AMA and its members....in violation of Section 1 of the Sherman Act *(49)*. The AMA appealed, but the Appellate Court in 1990 upheld the ruling and the Supreme Court let the ruling stand. In his book *Reclaiming Our Health,* John Robbins has given a detailed documented account of consequences of the AMA's abuse of power, its "befriending" relationships with political apparatus, pharmaceutical, tobacco, and other industries *(49)*.

In its total faith in drugs and surgery, the establishment has essentially ignored the role of nutrition in health *(51,52)*. Nutritional education in medical schools and residency programs has been at best marginal and inadequate according to the recent report to Congress *(53)*. Many practicing physicians feel that they lack the skills to provide nutritional information to their patients *(54)*.

The recognition of the need to completely revamp the current healthcare system in the report "Healthy People 2000", produced by Public Health Service, Department of Health and Human Services, increasing use of CAM modalities by the people of this country, increasing number of US physicians speaking out against the AMA's self-serving performance, and creation of OAM at NIH in 1992 has led the medical establishment to relax its views on CAM therapies and practices from "non-scientific and irrelevant" to "needing investigations."

The Resident Physician Section of the AMA, at its iterim meeting in December 1995, passed a resolution on alternative medical treatments that encourages the AMA's resident physician members to support the scientific investigation of alternative medical techniques *(55)*. Views on alternative medical treatments are also changing among the primary care physicians as indicated by the recent survey *(56)*. According to this survey, 57% of the physicians surveyed are willing to encourage the use of some unconventional therapies for patients who raise the possibility of unconventional therapy.

Medical schools across the United States are taking notice of the increasing interest in CAM modalities. Many of the schools are offering courses and seminars in CAM areas. There are over 30 medical schools in the U.S. now offering some CAM educational classes to complement their traditional training *(57)*. In the last couple of years, the educational aspect of CAM modalities has been greatly enhanced by several highly visible national and international conferences on CAM modalities. These conferences have been sponsored by various conventional health organiza-

tions, including medical schools, medical publishers, HMOs and hospitals *(58,59)*.

Even the FDA which came down hard on the supplier and healthcare professionals *(60)* who recommended the use of dietary supplements for health or illness, and now recognizing the demand and need of American people and manufacturers of the supplements, has relaxed the restriction it had imposed on their use. In October of 1994, it passed the Dietary Supplement Health and Education Act, which clarifies and limits the FDA's role. Although the FDA retains authority to act against products it can prove are unsafe, toxic, unsanitary, or adulterated, the Act provides for statements of nutritional support on supplement labels and third-party literature without the manufacturer having to seek FDA approval first, as long as they can substantiate claims.

The most important and significant outcome of the Act is that for the first time it gives dietary supplements a legal definition that distinguishes them from drugs or food additives. This unique definition provides the necessary mechanism for developing regulation of health claims in the future, and ensures that products will continue to be available without having to go through the multi-million-dollar approval process required by the FDA for patented drugs.

Many conventional hospitals, recognizing the need to incorporate Mind–Body–Spirit (consciousness) approaches, are creating their own centers or affiliating themselves with centers practicing CAM modalities. To just name a few: The Harvard University Medical School with its Mind/Body Institute at Deaconess Teaching Hospital has been a pioneer in offering intensive courses on alternative medical practices. Columbia University College of Physicians and Surgeons has the Rosenthal Center for Alternative/Complementary Medicine. It provides resources for both physicians and patients who seek information of CAM modalities. The Arizona Center for Health and Healing serves as a teaching and training center in CAM modalities for the University of Arizona School of Medicine.

Many medical institutions just a few years ago would have been considered "weird" to have given any importance to patient–doctor relationships and communication in healing process—long a hallmark of CAM practices—but are now offering training in physician–patient relationships and communication.

Physicians frustrated with the conventional healthcare model and medical establishments, and sensing the need and opportunity, have taken it upon themselves to create integrated healthcare centers that include the best of both conventional and CAM modalities, for example, the American Holistic Centers founded by Dr. David Edelberg. There currently are five centers, three in the Chicago area and one each in Denver and Boston. These centers provide services of CAM practitioners under the supervision of physicians. Other examples of such integrated healthcare include the Chopra Center for Well Being in La Jolla, California, founded by Deepak Chopra, M.D. and David Simon, M.D., and The Columbia-Presbyterian Complementary Care Center in New York City, founded by Melmet Oz, M.D. and Jerry Whitworth, R.N., C.C.P.

Healthcare policies in this country are governed by Boards of Health. These Boards are a fundamental and integral part of the medical establishment and the membership in these boards are restricted to conventional physicians. However, in 1996, for the first time in the United States, a Naturopath, Joseph Pizzarono, Jr., N.D. was appointed to serve on the Seattle-King County, Washington Board of Health. This certainly reflects the beginning of a changing attitude of the medical establishment.

CAM and Managed Healthcare Organization

According to the *Newsweek* special report *(61)*, as of June 1996, the Health Maintenance Organization's (HMO) enrollment had 53.3 million members, over 20% of the population. It is estimated that an additional 50 million people will be enrolled by the

year 2000. HMOs are growing so rapidly that they are transforming the healthcare system. For both, public and private purchases of health insurance, the question is simply which plan to select, rather than whether to shift traditional health-insurance coverage to managed care. The current growth in the managed-care industry has been largely in for-profit organizations, and even those historically nonprofit organizations, such as Blue Cross and Blue Shield have switched to for-profit status. This status change has forced the HMOs to be cost-conscious, and they have instituted many plans, including discounted fee-for-service and capitation (paying physicians and hospital a fixed amount per person enrolled) to reduce their cost of providing healthcare to enrolled members.

Today, the HMOs are increasingly willing to examine ways to reduce healthcare costs. The inherently "low-tech," preventive, and cost-effective CAM modalities have caught the attention of some HMOs to consider them for coverage in their plans. Mutual of Omaha has made Dr. Dean Ornish's Program for Reversing Health Disease a reimbursable benefit for any patient with coronary artery disease covered under its major medical policy. The program uses diet, meditation, exercise, and support groups to reverse heart disease. Mutual of Omaha has claimed it saves about $6.50 for every dollar it spends covering nonstandard treatments. American Western Life Insurance Company's wellness plan covers acupuncture, physical therapy and spinal treatments; other services may either be reimbursed or provided at discount. However, the benefits for the alternative therapies have dollar limits. The Western Life Insurance Company is now owned by Prime Care Health Network, Inc. and this year it will start providing these and other CAM coverages in several US states. Blue Cross of Washington and Alaska provides coverage for many CAM modalities as required by the state law. The plan provides for 50% of the cost up to $500 per year. Beginning in January of 1997, Oxford Health Plans will offer CAM programs to members in Connecticut, New York, and New

Jersey through a credentialed network. With the help of a board of medical consultants, Oxford developed a system of credentialing CAM providers. Thus far, Oxford's plan provides the broadest coverage of CAM therapies. It includes four components: a large network of credentialed CAM providers; a benefit plan that includes coverage for CAM services that can be purchased as a supplement to regular Oxford coverage; a mail-order service for purchasing CAM medicine products, vitamins, and remedies; and information service to help members understand the CAM strategies used for various illnesses. Oxford's CAM network is composed of acupuncturists, massage therapists, chiropractors, registered dietitians, clinical nutritionists, yoga instructors, and naturopathic physicians in Connecticut, but not in New York and New Jersey because naturopaths are not licensed in these states. Among the other insurance carriers covering some CAM modalities on the West Coast include Kaiser Permanente and Prudential Insurance Company of America.

Alternare of Washington, Inc., a credentialing service organization providing contractual CAM-practitioner credentialing to various HMOs, has come up with a "smart card" technology to allow patients direct access to CAM therapists at a discounted rate. Another organization, called Alternative Health Benefit Services (AHBS), negotiates and develops alternative health plans that are underwritten by other companies. The AHBS also get involved in marketing and some aspect of administration of these plans. The Alternative Health Plan features comprehensive major medical coverage, as well as partial reimbursement for CAM modalities.

It appears that as CAM-practitioners credentialing becomes standardized, many HMOs will follow the footsteps of the pioneers in providing coverage of CAM therapies in their healthcare plans. In fact, a recent report titled "Health Maintenance Organization and Alternative Medicine: A Closer Look by the Landmark Healthcare Company of Sacramento, CA found that 58%

of HMOs surveyed have plans to reimburse their members for alternative medical treatments in the next one to two years. Details of reimbursement policies of various HMOs and insurance companies for CAM modalities has recently been reviewed by Nancy Moore *(62,63)*.

CAM and NIH Research Funding

In 1990, after three years of extensive dialog involving more than 10,000 individuals, the U.S. Department of Health and Human Services, Public Health Service, produced a 700-page report, "Healthy People 2000" *(25)*. The report represented the work of 22 expert groups, a consortium with nearly 300 organizations and all the state Health Departments. The report recommended the need to revamp completely the current approach to healthcare. It enumerated the challenges and goals for improving the nation's collective health by the year 2000, and concluded that the health of people is measured by more than death rates. It comes from an improved quality of life and reducing unnecessary suffering, illness and disability. Thus, health is measured by people's sense of well-being. Further, it stated that "health of the nation is measured by the extent to which the gains are accomplished for all the people" *(25)*. To reach this goal, the report called for "mobilizing the considerable energies and creativity of the nation in the interest of disease prevention and health promotion" as an economic imperative. It called for investigating "alternatives" to current "disease care" approaches that might be best mobilized to help fight the chronic diseases crisis of the nation.

The collective medical knowledge and wisdom of the world contained in CAM modalities, with its emphasis on mind–body–spirit approaches that promote disease-preventing healthy lifestyles, self-responsibility for health, and linkage of individual health with community health, appears to have a ready solution

for the nation's healthcare crisis of chronic diseases. Millions of health-conscious Americans, realizing the limitation of the current healthcare system, are spending billions of dollars on CAM modalities to address their healthcare needs *(4)*. If, as a nation, we are to address this massive healthcare crisis that is consuming over three-fourths of the national healthcare cost of nearly $1.4 trillion, we must shift massively the tax-payer's research dollars to the NIH from "Diseasecare" fields to "Healthcare" fields of CAM modalities.

In 1992, the Congress established the OAM at the NIH with an annual budget of $2 million, to be used to investigate the potential of promising alternative therapies. This is hardly adequate funding for the task, but a step in the right direction. Since the OAM's 1992 meager funding, it has improved a bit, reaching $12 million in 1997. Even with this meager funding, the OAM has made significant progress in initiating several CAM research projects at various educational institutions. It has also created 10 CAM research centers across the nation to investigate CAM approaches in different chronic disease fields. The centers are serving as the nucleus for CAM investigators and practitioners in their respective areas. These centers of OAM and its existence at NIH has greatly enhanced the "outlook" of CAM modalities and they are beginning to attract attention of many biomedical scientists and healthcare professionals. These dedicated individuals appear to be ready to accept the challenge of the chronic-disease crisis facing the nation.

Mobilizing biomedical-research funds to CAM areas would necessarily increase the research interest of healthcare scientists and professionals in the CAM fields. In 1997, NIH will spend nearly $12 billion for biomedical research of which only 0.1% will be made available to investigate CAM modalities. Indeed, a meager sum. We must resolve this dichotomy of our understanding of need and action. If we are to reverse the chronic-disease crisis, we must rapidly increase the percentage of NIH funding to CAM modalities.

Ethics Of Healthcare

Ideally, the healthcare ethics should be governed by human needs and values. In other words, the healthcare decisions should encompass the biological/physiological needs, psychological needs, social needs, and spiritual needs based on the cultural context of an individual. The principle of Free and Informed Consent,

> To protect the basic need of every human person for healthcare and the person's primary responsibility for his or her own health, no physical or psychological therapy may be administered without the free and informed consent of the patient, or, if the patient is incompetent, of the person's legitimate guardian acting for the patient's benefit and, as far as possible, in accordance with the patient's known and reasonable wishes; *(64)*

represents the most important consideration in medical ethics when decisions are carried out in accordance with human needs and values in mind.

The current healthcare ethics has largely been governed to accommodate evolving science, technology, and the legal system, and the basic biomedical belief that human beings can be considered as machines made up of parts and organ systems. Therefore, the current healthcare system mainly concerns itself with treating illnesses by fixing, replacing or modifying these parts and organs with drugs and/or surgery and other technological procedures so as to restore "normal" physical functioning to the best degree possible. The healthcare system in the United States has become extremely sophisticated technically, requiring physicians and other healthcare professionals to have an expanded degree of training and specialization, and making them more technocratic rather than caring, compassionate, and service-oriented healthcare professionals. The technocratic approach of the healthcare system is intimidating, and it is beyond the under-

standing of most Americans to have any meaningful interaction and input for the treatment being chosen. The system has become very impersonal and both patient and healthcare professional alike feel frustrated and used. Moreover, the healthcare-delivery system has largely become a corporate business, often with technocrats as investing partners. Obviously, these corporate healthcare-delivery systems operate with a set of values and goals designed to enhance profits, but not health, and thus ethics becomes a secondary issue.

Total disregard by this impersonal healthcare system of the most important consideration in medical ethics, the principle of free and informed consent, is illustrated by a New York Times article entitled, "Making A Living Off the Dying" *(65)*.

The surgeon father of the writer, who had enjoyed good health all his life, was diagnosed with terminal pancreatic cancer at the age of 75. Knowing the impending consequences of the diagnosis, the son broke down. The father held his son's hand and whispered, that "everything will be OK, Norman. I have been a surgeon for almost 50 years—in that time I have seen physicians torture dying patients in vain attempts to prolong life. I have taken care of you most of your life. Now I must ask your help. Don't let them abuse me. No surgery, no chemotherapy." Dr. Norman Paradis assured his father that nothing like that would happen to him and accordingly, he instructed the attending physician and the hospital staff that his dying father only wanted and was only to receive medications to make him comfortable. To his dismay, he learned that soon after his departure from the hospital his father was subjected to a series of surgical and radiological procedures.

Dr. Paradis wrote, "I quickly realized what was going on. Consulting surgeons get paid thousands of dollars an hour when they decide to operate. So that was what they were deciding to do. It's an old story of inflated fees charged by sub-specialists with procedure-based practice."

Once again, he reminded his father's physician that what was being done to his father was futile, painful, and debilitating,

and that the procedures were not wanted by his father or anyone else in the family. He insisted that his father be cared for only by internists who had no incentive to do anything but make him comfortable. The attending physician assured him of that request. Despite Dr. Paradis's efforts, the series of procedures continued to be performed. He wrote, "When my brother, a lawyer arrived, he found our father in a hallway where he had been left after a test. He pleaded, 'they are treating me like an animal. Please get me out of here". With difficulty, both the brothers contacted the physician in charge and reminded him of the legality of performing procedures without consent and they were assured by the physician in charge that things would improve. No sooner had they departed from the hospital, when the doctors once again began giving the father unnecessary "billable high-tech therapy" that could not possibly cure him or relieve his pain. Many things had been done simply to correct problems caused by earlier therapies. When their mother put their father on the phone, he was incoherent. At that point, the brothers arranged a conference call with the hospital administrator and Chief of Staff. The surgeons were "too busy" to come to the phone. "Despite our clear instructions, you have continued to perform invasive procedures on our father", the lawyer son said. "He is now incompetent so we are invoking our power of attorney and explicitly forbidding you from doing anything that is not directed at relieving his suffering."

That night, however, their father was subjected to yet another surgery. Angry and desperate, the brothers tried to transfer their father to another hospital or to a hospice, but each time they arranged for him to be moved, a test or a procedure would be performed, making him temporarily unable to be transported. Once again, after they found their skeletal and barely alive father sitting alone in a hallway after yet another test, the family was finally able to move him to a nearby hospice. He died the next morning.

Medicare had paid more than $150,000 on a patient who needed only a bed and some morphine, Dr. Paradis wrote. When

he called to file a complaint against the hospital, Paradis was told by the Medicare Inspector General's Office that the billing for unauthorized procedures was a violation but in that state there are so many fraud cases over millions of dollars that cases involving a mere $150,000 could not possibly be investigated.

Unfortunately, this is not an isolated case. It represents a pattern of care in our technocratic healthcare system, particularly for people afflicted with terminal illnesses. If a doctor and lawyer could not get decent and humane care for a doctor, what chance would the average American have?

The medical establishment in general, and the cancer establishment in particular, has ignored potentially useful alternative therapies by simply labeling them as "unproven therapies" without any and/or proper investigation *(33,66,67)*. A survey *(67,68)* showed that most oncologists will not allow chemotherapy to be given neither themselves nor their family members for cancer treatment. However, they continue to treat the American people with chemotherapy despite its ineffectiveness and unacceptable toxicity for the treatment of most cancers, because it is considered as an approved cancer treatment by the medical establishment.

One of the reasons for the increasing popularity of CAM therapies and practices, particularly for chronic conditions, including cancer, is its caring, compassionate, and humane approach to treatments. Seventy to ninety percent of the world's people rely on CAM therapies and practices for their healthcare needs *(29)*, and the use of many of these CAM modalities is gaining popularity world wide, both in terms of increased number of practitioners and individuals consulting them *(69)*. Most of these therapies and practices have evolved from various ancient medical systems of the world. The ancient systems clearly understood that health represents optimal functioning of the human organism to meet biological, psychological, social, and spiritual needs. Therefore, in general, the CAM practitioners are concerned with healing the whole person in functional terms on an individual basis. In this approach, the practitioner, patient,

and the process of intervention plays an integral role in the healing process. CAM practitioners emphasize the empowerment of patients in the healing process, which in turn enhances the quality of life. In this model "cure" and "healing" are distinctly different. "Cure" basically reflects the physical reality; that is, the body is free from specific symptoms and one is returned to a familiar state of function. "Healing" occurs at different levels of human existence. One can be healed emotionally, psychologically, socially and spiritually without physically being cured of specific symptoms or disease.

In comparison to the United States, the European medical establishment is much more open to the CAM modalities and people are freely allowed to use CAM approaches for their healthcare needs. Perhaps it is one of the reasons that these countries have much less expensive healthcare systems than the United States and longer life expectancies.

The crisis of medical ethics and chronic diseases associated with the technocratic healthcare system based on the biomedical model suggests that the model needs to be expanded to include integrative mind–body–spirit approaches of CAM therapies and practices. Dacher *(70)* proposed an expanded alternative model of health and healing for reorienting primary care by going from the assumption of the biomedical model of objectivism, determinism, and positivism to dynamism, holism, and purposefulness. This expanded paradigm emphasizes the quality and character of the interrelationships that contribute to the healing process and provides an indication of what is necessary to shift to a new paradigm for integration, as opposed to integration within the "biomedical" paradigm. In Dacher's model of multidimensional healing, a patient would be considered by the medical provider from the perspective of homeostasis or adaptive capacity; treatment, symptoms, and findings; mind-body attitudes and lifestyle; and spiritual meaning or purpose. These factors are utilized to formulate a comprehensive health plan, rather than simply physiologically based diagnosis.

The healthcare crisis and other modern social ills of our society have challenged us to examine the Newtonian scientific model of the 20th century that has served us so well. As we approach a new millennia, the working scientific model must be changed to a new scientific model that incorporates the quantum uncertainties. The 21st century will belong to the science of consciousness.

Glossary of Complementary/ Alternative Therapies

Acupressure: Based on the principles of acupuncture, this ancient Chinese technique involves the use of finger pressure (rather than needles) on specific points along the body to treat ailments such as tension and stress, aches and pains, menstrual cramps, or arthritis. The system is also used for general preventive health care.

Acupuncture: In acupuncture, fine needles are inserted at specific points to stimulate, disperse, and regulate the flow of chi, or vital energy, and restore a healthy energy balance. Often used in the United States for pain relief, acupuncture is also used to improve well-being and treat acute, chronic, and degenerative conditions in children and adults.

Alexander Technique: Developed by actor F. Matthias Alexander, who created the method after concluding that bad posture was responsible for his own chronic voice loss. Practitioners, using gentle hands-on guidance and verbal instruction, teach simple, efficient ways of moving as a means of improving balance, posture, coordination and to relieve tension and pain.

Applied Kinesiology: Applied kinesiology is the study of muscles and their movements. It is a system that uses muscle testing procedures, in conjunction with standard methods of diagnosis, to gain information about a patient's overall state of health. Practitioners analyze muscle function, gait, and other struc-

tural factors in addition to inquiring about lifestyle factors that may be contributing to a health-related problem. Nutritional supplements, muscle and joint manipulation, and lifestyle modification (including diet and exercise) may then be used as a part of treatment plan. Applied kinesiology is used by health-care providers who are licensed to diagnose, such as chiropractors, osteopaths, dentists, and medical doctors.

Aromatherapy: Aromatherapy uses essential oils extracted from plants and herbs to treat conditions ranging from infections and skin disorders to immune deficiencies and stress. Essential oils are widely used throughout Europe and a system of medical aromatherapy is currently practiced in France.

Aston-Patterning: Founded by Judith Aston, director of the Aston Training Center in Incline Village, Nevada, and former professor of dance and movement, this method is an integrated system of movement education, bodywork, and environmental evaluation. In specifically designed sessions, teacher and client work together to reveal and define the body's individual posture and movement patterns while training the body to move more efficiently and effortlessly.

Ayurvedic Medicine: Practiced in India for the past 5,000 years, Ayurvedic medicine (meaning "science of life") is a comprehensive system of medicine that combines natural therapies with a highly personalized approach to the treatment of disease. Ayurvedic medicine places equal emphasis on body, mind, and spirit, and strives to restore the innate harmony of the individual.

Barbara Brennan Healing Science: Developed by physicist, teacher, and healer Barbara Brennan, this spiritual healing system seeks to reorganize and heal the client's energy field. Using both hands-on techniques and other approaches, the healer works to clear the client's field of unhealthy and blocked energies, charge depleted areas, repair distorted patterns, and balance the entire field. The goal is to promote health and healing on physical, emotional, mental and spiritual levels.

Bioenergetics: Bioenergetics hold that repressed emotions and desires affect the body and psyche by creating chronic muscular tension and diminished vitality and energy. Through physical exercises, breathing techniques, verbal psychotherapy, or other forms of emotional-release work, the therapist attempts to loosen this "character armour" and restore natural well-being.

Biofeedback: Biofeedback training teaches a person how to change and control his or her body's vital functions through the use of simple electronic devices. Biofeedback is particularly useful for learning to reduce stress, eliminate headaches, control asthmatic attacks, recondition injured muscles, and relieve pain.

Bonnie Prudden Myotherapy: Developed by fitness expert Bonnie Prudden in 1976, this bodywork method is intended to relax muscle spasms, improve circulation, and alleviate pain. The practitioner, using elbows or knuckles of the fingers, applies pressure for several seconds to "trigger points"—highly irritable spots on muscle tissue that may radiate pain to other areas. Clients also perform specific exercises for the freed muscle.

Chi Gong: Combines movement, meditation, and breath regulation to enhance the flow of vital energy in the body, improve blood circulation, and enhance immune function. Because Chi Gong can be used by the healthy as well as the severely ill, it is one of the most broadly applicable systems of self-care in the world. In China, it is estimated that 200 million people practice Chi Gong every day.

Chinese Oriental Medicine: An ancient method of health care that combines the use of medicinal herbs, acupuncture, food therapy, massage, and therapeutic exercise. It has proven effective for many conditions, including chronic degenerative disease, cancer, infectious diseases, allergies, childhood ailments, heart disease, and AIDS.

Chiropractic: Through adjustments of the spine and joints, chiropractors can influence the body's nervous system and natural defense mechanisms in order to alleviate pain and improve general health. Because of it's effectiveness in treating back prob-

lems, headaches, and other injuries and traumas, chiropractic has become the second largest primary health care field in the world.

Chiropratic Network: A form of chiropractic that views the spine as a powerful "switch-board of consciousness." The method is based on the belief that the spinal adjustment can serve to unify the physical, emotional, and mental body with a universal intelligence or consciousness.

Craniosacral Therapy: Manipulates the bones of the skull to treat a range of conditions, from headache and ear infection to stroke, spinal cord injury, and cerebral palsy. For decades various forms of cranial manipulation have been used to improve overall body functioning, and today CranioSacral therapy is gaining acceptance by health professionals worldwide as a successful treatment modality.

Deep Tissue Bodywork: A general term for a range of therapies that work to "unstick" the body's connective tissues and/or muscles to encourage them to function properly again. Among the conditions deep tissue bodywork treats are whiplash, low back and neck pain, and degenerative diseases, such as multiple sclerosis.

Do-In: An ancient macrobiotic exercise practice that macrobiotic proponent Kushi introduced into the United States in 1968. The Do-In exercises were developed over centuries in the Oriental religions of Shintoism, Hinduism, Taoism, and Buddhism. Although they are physical practices and their purpose is to produce physical health, spiritual harmony with the universe is the ultimate goal.

Esalen Massage: A form of massage, when given at the Californian Esalen Institute is done on a huge cliff overlooking the Pacific Ocean. Esalen massage is a hybrid style, blending Swedish massage with aspect of other bodywork techniques such as Aston-Patterning, craniosacral balancing, deep tissue massage, Feldenkrais, Rolfing, and the Trager Approach.

Feldenkrais Method: Combines movement training, gentle touch, and verbal dialog to help create freer, more efficient move-

ment. Feldenkrais takes two forms: individual hands-on sessions, wherein the practitioner's touch is used to address the student's breathing and body alignment; and in a series of classes of slow, nonaerobic motions, students relearn improved ways their bodies can move. The Method is frequently used to treat stress and tension, to prevent recurring injury, and to help athletes and others improve their balance and coordination.

Flower Essences (Bach Flower): The emotions play a crucial role in the health of the physical body. Flower remedies directly address a person's emotional state in order to help facilitate both psychological and physiological well-being. By balancing negative feelings and stress, flower remedies can effectively remove the emotional barriers to health and recovery.

Focusing: This self help tool is based on the premise that information about one's life issues can be accessed through so-called felt senses in the body. This skill can be used alone or in partnership with someone else for resolving day-to-day issues (such as decision-making), negotiating profound changes (such as recovery from abuse), and fostering spiritual development.

Guided Imagery: By using the power of the mind to evoke a positive physical response, guided imagery can reduce stress and slow heart rate, stimulate the immune system, and reduce pain. As part of the rapidly emerging field of mind/body medicine, guided imagery is being used in various medical settings, and when properly taught, can also serve as a highly effective form of self-care.

Hellerwork: Developed by former aerospace engineer (and one-time Rolf Institute president) Joseph Heller, this technique combines deep-tissue muscle therapy and movement reeducation with dialogue about the emotional issues that may underlie a physical posture. Participants go through eleven 60–90 minute sessions stressing the mind–body connection, Hellerwork is used to treat chronic pain or to help "well" people learn to live more comfortably in their bodies.

Herbalism: Is the most ancient form of health care known to humankind. Herbs have been used in all cultures throughout history. Extensive scientific documentation now exists concerning their use for health conditions, including premenstrual syndrome, indigestion, insomnia, heart disease, cancer and HIV.

Holistic Medicine: A broadly descriptive term for a healing philosophy that views a patient as a whole person, not just a disease or a collection of symptoms. In the course of treatment, holistic medical practitioners may address a client's emotional and spiritual dimensions as well as the nutritional, environmental, and lifestyle factors that may contribute to an illness. Many holistic medical practitioners combine conventional forms of treatment (such as medical surgery) with natural or alternative treatments.

Holistic Psychotherapy/Counseling: This broad category encompasses a range of practitioners, from career counselors who offer advice and information to psychotherapists who treat depression, stress, addiction, and emotional issues. Formats can vary from individual counseling to group therapy. In addition to verbal counseling techniques, some holistic therapist may use bodywork, ritual, energy healing, and other alternative modalities as part of their practice.

Homeopathy: A low-cost, nontoxic system of medicine used by hundreds of millions of people worldwide. It is particularly effective in treating chronic illnesses that fail to respond to conventional treatment, and it is also a superb method of selfcare for minor conditions, such as the common cold and flu.

Hydrotherapy: Is the use of water, ice, steam, and hot and cold temperatures to maintain and restore health. Treatments include full-body immersion, steam baths, saunas, sitz baths, colonic irrigation, and the application of hot, and/or cold compresses. Hydrotherapy is effective for treating a wide range of conditions and can easily be used n the home as part of a self-care program.

Hypnotherapy: Used to manage numerous medical and psychological problems. Hypnotic techniques can help a person

stop smoking, overcome alcohol and substance abuse, and reduce overeating. Hypnotherapy is also effective in treating stress, sleep disorders, and mental health problems, such as anxiety, fear, phobias, and depression.

Infant Massage: Taught to new parents by trained instructors, infant massage practices are designed to enhance the bonding between parent and baby. As preventive therapy, infant massage can help strengthen and regulate a baby's respiratory, circulatory, and gastrointestinal functions, often relieving gas and colic while relaxing both parent and child.

Iridology: A diagnostic system based on the premise that every organ has a corresponding location within the iris of the eye, which can serve as an indication of the individual's organ health or disease. Iridology is used by naturopaths and other practitioners, particularly when diagnosis achieved through standard methods is unclear.

Jin Shin Do Body/Mind Acupressure: Developed by psychotherapist Iona Marsaa Teeguarden, Jin Shin Do combines acupressure, Taoist yogic breathing methods, and Reichian segmental theory (which addresses how emotional tension affects the body), with the goal of releasing physical and emotional tension and "armoring." It aims to promote a pleasant trance in which the participant can address the emotional factors that may underlie various physical conditions.

Jin Shin Jyutsu: An Oriental system intended to harmonize the flow of energy through the body. The system holds that tension, fatigue, or illness can trap energy in the body's 26 "safety energy locks". Practitioner use their hands to restore balance and reduce stress. Jin Shin Jyutsu is not a form of massage, as it does not involve physical manipulation of the muscle.

Midwifery: Midwives provide education and support during pregnancy, assist the mother during labor and delivery, and provide follow-up care. Practitioners of childbirth support include childbirth educators, childbirth assistants, and doulas (women labor coaches who also provide postpartum home care). In some

states midwives can attend home births or practice in birthing clinics in hospitals. Some midwives are also licensed to provide "well-women" gynecological care, including screening tests and birth control.

Muscle Therapy: This general term incorporates a range of bodywork methods and practices that have a therapeutic (not simply relaxing) intent. Practitioners stress client education and follow-up. Among the conditions muscular therapy addresses are chronic back pain, headaches, tension, and emotional illnesses.

Naprapathy: Practitioners of this hands-on-healing system manipulate the muscles, tendons, and ligaments of the body in order to alleviate tension and promote fluidity of motion. Many naprapaths also make dietary recommendations because they believe that the chemistry of the body must, like its connective tissue, be in balance.

Naturopathic Medicine: Treats health conditions by utilizing the body's inherent ability to heal. Naturopathic physicians aid the healing process by incorporating a variety of alternative methods based on the patient's individual needs. Diet, lifestyle, work, and personal history are all considered when determining a treatment regimen.

Neurolinguistic Programming (NLP): Helps people detect and reprogram unconscious patterns of thought and behavior in order to alter psychological responses and enhance the healing process. NLP has provided results for people suffering from various conditions, including AIDS, cancer, allergies, arthritis, Parkinson's disease, and migraine headaches.

Neuromuscular Therapy: Emphasizes the role of the brain, spine, and nerves in muscular pain. One goal of the therapy is to relieve tender congested spots in muscle tissue and compressed nerves that may radiate pain to other areas of the body.

Nursing, Holistic: More a philosophy than a series of practice, holistic nursing is embraced by registered or licensed nurses who seek to care for the body, mind, and spirit of the patient. Some holistic nurses work in independent practices, offering

primary and chronic care that incorporates a variety of alternative methods, from homeopathy to therapeutic touch.

Occupational Therapy: Occupational therapists help similarly afflicted patients as physical therapists (*see* Physical Therapy), to regain the skills needed to resume an independent, productive life.

Ohashiatsu: A system of physical techniques, exercise, and meditation used to relieve tension and fatigue and induce a state of harmony and peace. The practitioner first assesses a person's state by feeling the hara (the area below the navel). Then, using continuous flowing movements, the practitioner presses and stretches the body's energy channels, working in unison with the person's breathing.

Ortho-Bionomy: Developed by a British osteopath, Ortho-Bionomy involves the use of noninvasive, gentle touch, along with dialogue and instruction in common movements, such as walking, sitting, standing, and reaching. Practitioners may also sometimes work with the energy field surrounding the person. The goal of the work is the student's enhanced well-being and empowerment, rather than physical healing per se.

Osteopathy: Is a form of physical medicine that helps restore the structural balance of the musculoskeletal system. Combining joint manipulation, physical therapy, and postural reeducation, osteopathy is effective in treating spinal and joint difficulties, arthritis, digestive disorders, menstrual problems, and chronic pain.

Physical Therapy: Concerned with health promotion, disability prevention, and promoting recovery from disabling conditions such as a bone fracture, head injury or stroke. Therapists use massage, exercise, electrical stimulation, ultra-sound, and other methods to help the patient regain functional movement.

Pilates Method: A full-body exercise system that emphasizes body alignment and correct breathing. With the help of an instructor, clients perform strength, flexibility, and range-of-motion exercises on specially designed equipment. The Pilates

Method may be performed by people of any age group or fitness level in order to improve their flexibility and range of motion, and people in physical therapy may use this method to aid in their recovery.

Physiatry: Doctors in this small and growing field have broad and extensive training in physical medicine. They recognize that most pain is muscular in origin and they use physical means, like stretching, massage, heat, cold and exercise to relieve it. Physiatry also uses some of the newest diagnostic tools, like thermography and electromyography. But the physiatrist's chief tool is touch.

Polarity Therapy: Asserts that balancing the flow of energy in the body is the underlying foundation of health. Practitioners use gentle touch and guidance in diet, exercise, and self-awareness to help clients balance their energy flow, thus supporting a return to health.

Pranayama: A science of breathing that deals with how breath energy can be integrated at different levels of human beings into a functional whole. It provides powerful tools for expanding one's awareness of various dimensions of body and mind as well as for use as a therapeutic modality.

Re-birthing: Also known as conscious-connected breathing (or by some practitioners as vivation), rebirthing is a technique in which the therapist guides clients through breathing exercises to help them re-experience past memories-including birth-and to let go of emotional tension long stored in the body.

Reflexology: Is based on the idea that specific points on the feet and hands correspond with organs and tissues throughout the body. With fingers and thumbs, the practitioner applies pressure to these points to treat a wide range of stress-related illnesses and ailments.

Regression/Past-Life Therapy: Based on the premise that many physical, mental, and emotional problems are extensions of unresolved problems from the past—whether from childhood traumas or from experiences in previous lifetimes. The practitio-

ner uses hypnosis (or altered states of consciousness) and relaxation techniques to access the source of this "unfinished business," and helps clients to analyze, integrate, and release past traumas that are interfering with their current lives.

Reiki: Practitioners of this ancient Tibetan healing system use light and hand placements to channel healing energies to the recipient. Although practitioners may vary widely in technique and philosophy, Reiki is commonly used to treat emotional and mental distress as well as chronic and acute physical problems, and to assist the recipient in achieving spiritual focus and clarity.

Rolfing: Developed by biochemist Ida P. Rolf, this technique used deep manipulation of the fascia (connective tissue) to restore the body's natural alignment, which may have become rigid through injury, emotional trauma, and inefficient movement habits. The process involves ten sessions, each focusing on a different part of the body.

Rosen Method: Developed by former physical therapist Marion Rosen, the Rosen Method combines gentle touch and verbal communication to evoke relaxation and self-awareness. Because the work can bring up buried feelings and memories, it is used as a tool for personal growth as well as pain relief.

Rubenfeld Synergy Method: Developed by healer Ilana Rubenfeld, The Rubenfeld Synergy Method uses gentle touch, movement, verbal exchange, and imagination to access memories and emotions locked in the body. The approach integrates elements of the Alexander Technique, the Feldenkrais Method, gestalt therapy and hypnotherapy. Because it combines bodywork and psychotherapy, The Rubenfeld Synergy Method may be used for specific physical and emotional problems or for personal growth.

Shiatsu: The most widely known form of acupressure, shiatsu has been used in Japan for more than 1000 years to treat pain and illness and for general health maintenance. Using a series of tech-

niques, practitioners apply rhythmic finger pressure at specific points in the body in order to stimulate *chi,* or vital energy.

Sports Massage: Sports massage is treated by a massage therapist with a specialized background in anatomy, physiology, and kinesiology. They work with athletes that are pushing to their limit. Pre- and post-event massage may prevent serious injury, increase range-of-motion, increase flexibility, and reduce soreness to these athletes.

Soma Neuromuscular Integration: This bodywork method seeks to improve posture, joint function, and body alignment through deep manipulation of the muscular and connective tissue. The ten-session process, which incorporates movement training and other adjuncts, also seeks to promote greater access to the functioning of each hemisphere of the brain. People with conditions, such as chronic back pain, arthritis, asthma, scoliosis, and headaches have sought relief from this method.

Structural Integration: A systematic approach to relieving patterns of stress and impaired functioning, structural integration seeks to correct misalignment in the body created by gravity and physical and psychological trauma. As in Rolfing, in ten sessions the practitioner used hands, arms, and elbows to apply pressure to the fascia, or connective tissue, while the client participates through directed breathing.

Swedish Massage: The most commonly practiced form of massage in Western countries, Swedish massage integrates ancient oriental techniques with modern principles of anatomy and physiology. Practitioners rub, knead, pummel, brush, and tap the muscles. Swedish massage is widely practiced; thus, practitioners will range greatly in training, technique, and length of session.

Tai Chi/Martial Arts: The martial arts are perhaps best known as means of self defense, but they are also used to improve physical fitness and promote mental and spiritual development. The highly disciplined movements and forms are thought to unite body and mind and bring balance to the individual's life. "Exter-

nal" methods (such as karate and judo) stress endurance and muscular strength, while "internal" methods (such as tai chi and aikido) stress relaxation and control. Tai chi has been used as part of treatment for back problems, ulcers, and stress.

Therapeutic Touch: Popularized by nursing professor Dolores Krieger, therapeutic touch is practiced by registered nurses and others to relieve pain and stress. The Therapeutic Touch practitioner "assesses" where the person's energy field is weak or congested, and then used his or her hands to direct energy into the field to balance it.

Trager Method: Developed by Milton Trager, M.D., this movement-education approach seeks to address the mental roots of muscle tension. By gently rocking, cradling, and moving the client's body, the practitioner encourages the client to see that physically restrictive patterns can be changed. Trager bodywork is meant to promote relaxation and increase mobility and mental clarity. It is used by athletes for performance enhancement, and by people with musculoskeletal and back problems.

Trigger-Point Therapy: Practitioners of this technique apply pressure to specific points on the body to relieve tension. Trigger points are tender, congested spots on the muscle tissue that may radiate pain to other areas. Though the technique is similar to shiatsu and acupressure, this therapy uses Western anatomy and physiology as its basis.

Yoga Therapy: Yoga therapy is an emerging field of practices that use yoga to address mental and physical problems while integrating body and mind. Practitioners work one-on-one or in group settings, assisting clients with yoga postures, sometimes combined with therapeutic dialog.

Zero Balancing: Zero balancing is a method for aligning body structure and body energy. Through touch akin to acupressure, the practitioner seeks to overcome imbalances in the body's "structure/energetic interface," which is said to exist beneath the level of conscious awareness. Zero balancing is often used for stress reduction.

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Abstract

Healthcare plans have traditionally covered standard medical care. This category includes therapies generally recognized as beneficial to patients by medical consensus, or, increasingly, in the last thirty years, particularly as pertains to therapies for life-threatening illness, includes therapies demonstrated effective through the results of scientifically adequate clinical trials. The experimental/investigational exclusion clause became part of most health care plan contracts by the mid-1970s. This exclusion clause recognized a division of responsibility. Healthcare plans covered standard therapies—those that had already been sorted out through medical consensus or clinical trial. The federal government, pharmaceuticals, and philanthropy covered the costs relating to the development of new and improved therapies as part of a social/public obligation or commercial interest. In the last 30 years, acceptance of new therapies into a benefit package has been increasingly contingent upon demonstration of their therapeutic worth through clinical trials producing usable outcome data. Therapies antedating that period are included based on medical consensus, which is usually reflected in drug or procedure compendia.

Gatekeeping by healthcare plans became publicly visible during the mid-1970s and involved the application of the experimental/investigational exclusion to unproven and untested therapies—usually quackery or "fringe" medicine. The courts generally upheld the exclusion from coverage of therapies that had no systemic process in place to study a therapy and produce reliable outcome information on whether it could be expected to benefit patients. Application of the exclusion in this fashion was consid-

ered to be appropriate for the wise use of premium dollars. With the erosion of federal support for treatment development through support of patient care costs for participating in clinical trials, the gatekeeper function has expanded beyond "fringe" medicine to the appropriate coverage of specific applications of high-technology medicine, such as high-dose chemotherapy with autologous, allogeneic, or cord-blood rescue while still in clinical trial.

Examination of cases involving "fringe" medicine vis a vis *standard therapies or those on clinical trial appears to demonstrate that the gatekeeper function has been applied evenhandedly to therapies regardless of their provenance. The underlying requirement for coverage is the level of objective, reliable, and verifiable data that is available on the approach and whether it has demonstrated that it can be expected to benefit the patient or that the patient will be participating in a scientifically adequate study that will produce information on the place of the therapy in the medical armamentarium. It would be unfair to have a double standard of gatekeeping for so-called "alternative" therapies. To win coverage as a basic benefit, "alternative" therapies should be expected to participate in systems, appropriate to their particular class of therapy, that will produce objective and verifiable data on patient benefit.*

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Healthcare Plans as Gatekeepers

Alternative Medicine

Grace Powers Monaco, J.D. and Gilbert Smith, J.D.

Introduction

Background

Gatekeeping is the term used to describe healthcare plans fiduciary responsibility to manage premium dollars in the best interests of the plan member *(1–4)*. This relationship is usually described in the plan document or master contract and the benefits are determined, increasingly, by employer preference, or by what can be accommodated within the premium base in indemnity or managed care programs. The health care plan is obligated by this contractual relationship to have a process in place providing access to medically necessary and appropriate care to its members. In theory, and usually in practice, accessible care for the individual member can be defined as benefits that are scientifically known and established by clinical trial or by consensus

medicine, i.e., generally accepted as beneficial by the medical community *(4–14)*. Accessible care also takes into consideration that the member in question must fit the profile of patients for whom benefit has been established:

> "...an effective intervention is one that improves a population of patients' health status. An appropriate intervention is one that can reasonably be expected to benefit a particular patient because he or she fits the profile of patients for whom it is effective" *(8)*.

Access can be described as including interventions that are expected to provide the opportunity for a positive benefit to the member and, in most plans, to inform future options through participation in appropriate clinical trials.

Why shouldn't payors simply cover any treatment that a provider proposes? Most importantly, payors have a fiduciary responsibility to manage their clients' premiums wisely *(1–4)*.This has been established in case law to include protection from fringe treatments *(12,15,16)*. Otherwise, payors would be forced to increase plan health care costs to the point that services would have to be cut back or eliminated altogether, to keep premiums affordable. Should the payor be relieved of this fiduciary responsibility when evaluating "alternative" or "unconventional" treatments, or should these alternative therapies be held to the same standard as other procedures? If a treatment hasn't been scientifically proven effective by application of a relevant system of objective evaluation and proof *(6,8,17,18)* or accepted as known to be effective through a medical-consensus process *(7,8)*—standards that are met by conventional treatments—shouldn't treatments not so established be obvious cost-containment targets?

Evenhanded Application of Evidence-Driven Standard for All Schools of Medical Thought

Aside from "cartoon characters," physicians decline to claim infallibility. Ethical physicians consider the patients'

interest paramount, meaning they welcome, expect, and encourage questions about appropriate protocols for treatment and usually take the initiative to schedule or encourage second opinions for patients needing to delve deeper. Rather than being threatened by other viewpoints, ethical physicians realize that their treatment options can be expanded and improved via the opinions of their peers.

The peer-reviewed medical literature, journals, medical newspapers, and the popular daily press are replete with lively exchanges among physicians commenting on treatment protocols and research, challenging each other's assumptions and making suggestions. There does not appear to be a parallel in the open discussion and reporting of exchanges among alternativists regarding their therapies' pros and cons and sacred cows. The comments of alternative medical providers appear to be largely defensive in tone. Among "alternativists," lively exchange in the journals, medical papers and press, appears, for the most part, to be restricted to cries of conspiracy, slander, witch hunt and the like, that appear whenever a regulatory agency requests adherence to rules and standards applicable to the practice of conventional medicine *(2,3,17)*.

Challenges to the gatekeeper function have usually involved controversial therapies, those procedures for which the benefits are not scientifically known (established by clinical trials or another objective standard of proof) or have not been accepted by a medical consensus process. Litigation invariably involves health plan members of precarious health status who have few options left. In these cases, the courts have generally concluded that:

1. Claims of cures are matters of public interest affecting the public health *(19,20)*.
2. Open discussion is essential to facilitate fully informed medical choices *(19,20)*.
3. Persons practicing highly controversial methods of dealing with disease can expect severe and detailed criticism *(15)*.

Courts have expressed concerns about the well-being of the body politic and its protection from fringe medicine, which can be attributed as follows as to the gatekeeping function:

1. It is applied with equal rigor to all controversial therapies, whether offered by mainstream medicine *(10,21–25)*, or alternativists *(1,10,15,16,26)*;
2. It is directed toward fulfilling the responsibility of the healthcare plan to use wisely its premium dollars for the benefit of all members *(1,4)*.
3. It presupposes and relies on the availability of some system of objective proof that methods and interventions can be expected to provide benefit, suited to the nature of the method or intervention *(4–14,18)*.

The gatekeeping principle requires an evidence or consensus basis for medical care methods *(8,13,14,19,22)*. This principle has been expressed and tested in court proceedings all the way up to the United States Supreme Court. In *United States v. Rutherford (27),* the Supreme Court rejected suggestions by promoters of laetrile, that laetrile, as a treatment of last resort, was not subject to the Federal Food Drug and Cosmetic Act (FDCA) and that terminally ill patients should have access to any unapproved product they wish. The Court found that the FDCA protects the terminally ill the same way it protects the rest of the populace by restricting access, except in the case of clinical trials, to products that have not demonstrated their potential therapeutic benefit. The Court clearly established that access to unproven/experimental drugs lay through participation in clinical trials *(1,9,17,27)*.

> The Federal Food, Drug and Cosmetic Act makes no special provision for drugs used to treat terminally ill patients ...We have no license to depart from the plain language of the act, for Congress could reasonably have intended to shield terminal patients from ineffectual or unsafe drugs... In the treatment of any illness, terminal or otherwise, a drug is effective if it fulfills, by objective indices, its sponsors claims of pro-

> longed life, improved physical condition, or reduced pain...For the terminally ill, as for anyone else, a drug is unsafe if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit ...there is a special sense in which the relationship between drug effectiveness and safety has meaning in the context of incurable illness...if an individual suffering from a potentially fatal disease rejects conventional therapy in favor of a drug with no demonstrable curative properties, the consequences can be irreversible ..construing Section 201(p)(1) to encompass treatments for terminal disease does not foreclose all resort to experimental cancer drugs by patients for whom conventional therapy is unavailing...[their access is to]...drugs intended solely for investigational use if they satisfy certain preclinical testing and other criteria....(558) That the Act makes explicit provision for carefully regulated use of certain drugs not yet demonstrated safe and effective reinforces our conclusion that no exception for terminal patients may be judicially implied *(27)*.

Requiring objective standards of proof of benefit has been consistently applied in cases involving health plan coverage of alternative therapies *(1,10,15,16,28)* as well as in cases involving conventional medical care *(13,14,23,25)*. In *Pirozzi v. Blue Cross Blue Shield of Virginia,* the court applied the standards criteria developed in fringe medicine cases to a case involving high dose chemotherapy with bone marrow rescue that was then in clinical trials: "...medicine...is always investigational and experimental in the sense that we have a potential for doing better and should investigate that potential" *(12)*.

Where Coverage Is Not Provided for Alternative Treatments, It Can Be Attributable to the Absence of Evidence-Based Systems of Proof

Lack of Evidence Based Standard Acknowledged by Alternativists

Satisfaction of the criterion of evidential or consensus support required by the gatekeeping principle, and which determines access to health-care plan coverage, does not appear to be cur-

rently attainable by many so-called "alternative" therapies. A variety of sources on the internal characterize therapies falling within the rubric of alternative and complementary medicine as possessing the following attributes *(28a)*:

1. Lacking sufficient documentation for the safety and effectiveness against specific diseases and conditions
2. Lacking a valid scientific base;
3. Not usually taught in medical schools,
4. Not usually reimbursable by health insurance plans.

When studies/systems of proof have produced data with internal and external validity on specific approaches, healthcare plans will have the objective reference they require to include these therapies in their offered services *(1)*. The *Odenwaller* case *(26)* involved immunoaugmentative (the Burton/Bahamas) therapy for cancer, which is listed as an "alternative" therapy by the Alternative and Complementary Health Practices Special Primary Interest Group (ACHP SPIG) of the American Public Health Association [APHA] *(29)*. In *Odenwaller (26)*, the court arbitrator declined coverage. He found that, as applied to the Burton therapy, there had been no experimental protocol, no clinical trial, and no systematic follow-up, and there was no indication that the clinic was capable of producing valuable medical or scientific information.

> If the unproven therapy is not included as part of a well-defined and ongoing program of research, experimentation and study that should ultimately contribute to the body of scientific and medical knowledge, the therapy is not reasonable and necessary for treatment *(26)*.

In *Zuckerberg (16)*, which involved the Gerson nutritional-therapy program, also an ACHP SPIG-listed alternative, the court reaffirmed the view espoused in *Odenwaller, supra,* that generally, healthcare-plan coverage was available only for therapies with objective proof of benefit:

> Our decision will insure that in treatment rendered on behalf of patients...effectiveness has been adequately demonstrated by studies conducted in accordance with appropriate scientific methodology before the resources of a major health insurer are utilized to support it *(16)*.

Note the specification was "appropriate" scientific methodology, which is in line with, and reinforces the plans of, the Office of Alternative Medicine (OAM) for development of criteria relevant to the specific type or class of therapy. European use of alter-native medicines is likewise circumscribed by systems of proof:

> Among the approval categories used by certain countries are the traditional use category and the known use category. The traditional use category does not mean approval: it means long-term historical use without side effects. Whether evidence should be based on reasonable certainty or on clinical trials is an issue for every botanical. Historical and chemical evidence might be sufficient. The WHO (World Health Organization) accepts traditional use *(30)*.

Although evidential systems for alternative therapies suggested for use in the United States are being developed, a possibility as a bridge system could be utilizing the evidence based system adopted in Germany. For example, for uses of botanicals, Commission E of Germany employs a doctrine of "reasonable certainty" for efficacy but "absolute certainty" for safety. The criteria for the doctrine of absolute certainty includes long-term, traditional, and historical use and scientific data—chemical, toxicological, pharmacological, clinical, epidemiological, or case history. The monographs under development by Professor Farnsworth and his colleagues at the University of Illinois at Chicago, covering 30 of 35 substances considered key in herbal use and currently under peer review, could also provide an authoritative template for payor reference *(31)*.

Initiatives of the National Cancer Institute (NCI) and the OAM

The National Institutes of Health (NIH) has characterized alternative medicine as an unrelated group of non-orthodox therapeutic practices, often with explanatory systems that do not follow conventional biomedical explanations. The absence of proof does not mean that proof is not attainable. One methodology employed to this end by the NCI is its "best case series" which provides guidelines for alternative therapists to follow in organizing their data in a way that makes clinical sense. If the initial series produces some positive results, the NCI will pursue further investigation.

The NIHOAM has been charged to determine, by objective scientific evaluation, the efficacy and safety of practices and procedures of unconventional medicine. It would be expected that therapies that can be tested according to the standards of scientific proofs, which generally apply to medical and preventive interventions, would be so tested. This does not require that approaches that cannot be tested accordingly be thrown aside, but does certainly require that the OAM place its imprimatur upon, and articulate processes that will yield reliable results, and provide assistance and encourage movement toward the implementation of those processes.

Attempts to Side-Step OAM Initiative

The OAM's determination that processes that can provide reliable outcome results be applied to alternative medicines has been under continual attack from persons within the ranks of the alternativists, who want business-as-usual, with proofs of validity based on nothing more than random, unsubstantiated accounts of success. To that end, the alternativists promoted legislation in the 105th Congress called the Access to Medical Treatment Act. The Access to Medical Treatment Act [(HR 2019/S1073)] would allow anyone to obtain any type of medical treatment he or she wants from any licensed medical doctor, osteopath, chiropractor, or naturopath qualified and licensed to perform the treatment, as long as there is no evidence that the treatment is dangerous and

the patient is informed of possible adverse effects, and advised that the treatment is not approved by the FDA.

The Act, however, put the onus on the Food and Drug Administration to produce data indicating that a product was dangerous, not on the practitioners to produce evidence that the therapy was viable. Congress declined to adopt this legislation, which appears to be an attempted end run around the determined structure/process development efforts of the OAM. Wayne Jonas, head of the NIH OAM, is reported to have testified at those hearings that the then-pending Access to Medical Treatment Act had no mechanism for systematic data collection to assure valid information concerning alternative medicine. He was reported to note that even when alternative modalities can be considered "safe," they can result in "indirect harm" by persuading patients to neglect therapies that have been established as effective *(32)*. An example of the dangers of the unwitting diversion of patients from therapies that can be effective are documented in court proceedings *(33)*. A patient with an obvious growing breast cancer lesion, previously untreated, had treatments administered based on urine and saliva tests that robbed her of essential fluids and ultimately created an electrolyte imbalance. It was found that by the time she was admitted to the hospital, the treatments had so seriously weakened her system that she was physically unable to undergo the chemotherapy that could have extended her life. As a result, Sybil died from complications attributed to the untreated breast cancer *(33)*.

Gatekeeper/Coverage Function Toward Alternative Methods in the Legal Literature and Judicial Case Law

Background: Definitions, Derivation, and Usability (2,3,34)

The terms alternative, unorthodox, complementary and nonconventional are often used interchangeably to describe therapies

that have not produced, by some objective standard, evidence for their effectiveness *(36)*. These approaches cater to public desires "for simple and easy (painless)ways to make disease disappear..." The variety of definitions may promote consumer confusion. At present the OAM, The American Public Health Association's Alternative and Complementary Health Practices' Special Primary Interest Group (ACHP SPIG), and a myriad of other entities found on the Internet, define alternative therapy by exclusionary characteristics of treatment, (i.e., negative characterisitic: what the therapy is not) *(36)*.

> ACHP SPIG understands this term to refer to interventions for improving, maintaining, and promoting health and well-being, preventing disease, or treating illness that are not part of a standard North American biomedical regimen of health care or disease prevention. "Standard" refers to practices commonly taught in schools of medicine or health sciences in North America or commonly covered by major insurers *(29)*.

In contrast, the American Cancer Society and the courts and regulators appear to define alternatives by positives (i.e., what the therapy is; what has evidential support). The American Cancer Society *(40)* has defined alternative as unproven or disproven methods and complementary as supportive therapies that are used to complement standard treatment, but that are sometimes used inappropriately. The definition of alternative, reported on the Internet as adopted by the National Institutes of Health as discussed on pp. 63–64 supra is in substance referenced as following nontraditional or unconventional ideas, methods existing outside the establishment *(40a)*.

The primary general and legal dictionary definitions of alternative, however, apply to "choices" and "options" to use in lieu of another, to substitute. Herein arises the ambiguity in communication and perception. The term "alternative" had a common use and understanding in medicine, long before the attempt began to craft a politically correct definition for these therapies began.

In standard medical use, reflected in a variety of court opinions cited herein *(15,16,19,20,26,40,43)*, alternative implies a choice between two courses of equal value: A case in point is *Moore v. Baker (38)*. In this case, the patient had sought treatment for blockage of her left carotid artery. The defendant physician recommended surgery and advised her of the risks of undergoing surgery. He did not advise her of an alternative treatment known as EDTA therapy, which is a listed ACHP SPIG alternative therapy *(28)*. The patient underwent surgery and suffered permanent brain damage. The patient filed suit, alleging malpractice because the doctor failed to advise her of EDTA therapy. A federal appeals court agreed with the trial court that Georgia's informed consent law does not require physicians to inform patients of all alternatives to surgery or even of those alternatives that are generally recognized and accepted by reasonably prudent physicians:

> . . . [a physician had] no duty to inform Moore about EDTA therapy because it is not generally recognized and accepted among the medical community as an alternative treatment for Moore's condition....The evidence overwhelmingly suggests that the mainstream medical community does not recognize or accept EDTA therapy as an alternative to a carotid endarterectomy in treating coronary blockages *(38)*.

Evidentiary Support Standard Applied to Alternative Medicine in Law/Commentary (2,3,17)

Healthcare plans traditionally only pay for medically necessary care, i.e., standard treatments whose place in medicine has been determined through controlled trials or through broad acceptance in clinical practice *(8,12,15,21,23–39)*. Insurers generally pay for therapy that is "reasonable or necessary," which has been defined as "wise in the light of facts known at the time rendered" *(4)*. Except for the growing number of healthcare plans paying for participation in meaningful clinical trials, healthcare

plans generally exclude payment for "experimental" or "investigational" therapies *(11)*. The objective evidence-based standard has been verified in numerous cases involving alternative therapies *(15,16,26,29)*.

A patient's desire to opt for therapy, outside of clinical trials, that is not established by the results-oriented outcomes from a system of effective evidence, can be accorded sympathy but certainly not deference *(15,16,29,41)*. Against the general weight of legal opinion, one court held anecdotal testimony that certain patients felt better, and believed such treatment had improved their condition, which has some relevancy to show that the alternative therapy—immunoaugmentative therapy—was necessary to fight cancer and is admissible, but only if the patient's observations are rationally based. The court indicated that this evidence would be neither valuable or relevant if the lack of scientific basis for the anecdotal testimony had been exposed by counsel *(40)*. In contrast to the weight of legal opinion is a long line of cases involving the FDA in which patient testimony was rejected as without any merit in establishing scientific safety or efficacy. As one court noted, it is simply not enough to show that some people, even experts, have a belief in [the] safety and effectiveness [of a particular drug]. A reasonable number of Americans will sincerely attest to the worth of almost any product or even idea *(15,18,29)*.

An objective and appropriate evidential-based system of data collection and outcome-reporting for alternative therapies, which is an OAM current objective, can facilitate coverage of alternative therapies that have provided objective data of support or that are participating in meaningful studies and support continued refusal to cover alternative therapies provided by proponents who refuse to cooperate in relevant clinical trials. As NCI has already demonstrated in applying its case approach, and as OAM is attempting to demonstrate, there can be evaluative approaches that will produce trustworthy data tailored to the specific class of alternative therapies. Dean Ornish's program for reversing heart disease is receiving acceptance by third party payors because he

has credibly documented its value. The usual excuses for refusing to submit a therapy to objective data collection/trial procedures has included:

1. Treating patients is more important than keeping medical records.
2. I can't divulge records because I have to protect the privacy of patients so I cannot permit outside review of records or procedures.
3. The trial is rigged to fail.

Alternative Therapies and Patient Bill of Rights

Shouldn't the quality of information that patients need in order to be protected against fraudulent, dangerous or nonproductive therapies be the same quality of information available from physicians on therapies that are considered standard treatment, through the consensus of medical opinion, or therapies that are in investigational clinical trials? Surely self-reporting via questionnaire by the user of the alternative therapy, a method employed by some proponents of "alternative" therapies for patients with terminal illnesses, and referred to in publicity for the method as participation in a clinical trial, does not rise to the level of objective proof of benefit and fair comment informing of the patient.

A patient's right to this quality of verified and verifiable information is recognized in the Proposed Patient Bill of Rights developed by the American Medical Association's Council on Ethical and Judicial Affairs, but can be found, in substance, in any patient bill of rights available through hospitals and patient-advocacy organizations:

1. The patient has the right to receive information.
2. Patients are entitled to know the benefits, risks, and financial costs of the treatment alternatives that are appropriate for their condition.
3. Patients should receive guidance from their physician regarding the optimal course of action.

4. Patients are also entitled to obtain copies of their medical records, to have their questions answered, to receive second, independent opinions and to be advised of potential conflicts of interest that their physicians might have.

This bill of rights applies to all physicians. It is not only applicable to physicians practicing generally accepted medicine or entering patients in well designed clinical trials. Both conventional and unconventional practitioners are held to the same standards under the Patient Bill of Rights.

The Patient Bill of Rights requires any practitioner to be aware of the optimal course of treatment for a specific condition and to be sure that the treatment options for which outcomes are scientifically known are referenced fairly along with "alternatives". The alternativist must be ready to answer all questions about the benefits, risks, and costs of his proposal and other alternatives and be able to demonstrate why the regimens suggested are "appropriate" for the patient. In addition, for example, if the "alternative" practitioner is selling his own brand of medicine from which he profits, then sending his work to his own laboratory, he must also be ready to disclose this information to the patient.

Litigation involving alternative-therapy treatment demonstrates misrepresentations about the nature of a treatment, its expected risks and benefits and overall outcome. This pattern of past conduct increases the demand for proof of benefit or acceptance through medical consensus before blanket inclusion in the basic benefit package of health care plans:

- The patient is informed that the combination of "dot" dosage chemotherapy with laetrile would provide the best of both worlds of medicine; the court found that it was dangerous because dot dosage chemotherapy would sensitize the patient to the chemotherapeutic agents used and preclude their future effective use if needed.
- Two natural therapists, treating a patient for breast cancer, performed urine and saliva tests and then devised a treatment

program consisting of nutritional supplements, hot and cold compresses, and up to 11 enemas and colonic irrigations a day, including apple, carrot, aloe vera juices, and castor oil. Cancer metastasized to her lungs and she began suffering from pulmonary edema, electrolytic imbalance, and a lack of oxygen in the blood, until she ultimately died of respiratory failure *(33)*.

- A masseuse applied deep massage on a leukemia patient's swollen spleen which burst, causing the patients death *(42)*. Patient had a medical history of kidney disease, heart disease and hypertension which were not diagnosed by the alternate therapist. Instead, the therapist supported the theory that the nutrition and laetrile program would be the most effective treatment. The therapy recommended mandated the release of cyanide that could have caused kidney failure and was the ultimate cause of death at autopsy *(43)*.
- Practitioner told his patients that the herbal salves would "draw out and break down the cancerous tumors" and that his black pepper teas would break up the cancer within. Both of these representations are false *(44)*.
- After attending a health fair, listening to and questioning "metabolic" practitioners about application to their child, the parents of a child with cancer provided him with massive doses of vitamin A under a natural, metabolic therapy program which resulted in a hospital admission with vitamin A-induced toxicities. The child made a complete recovery after standard conventional corrective care *(45)*. Other toxicities have been noted in natural metabolic therapy programs over the years *(46–49)*.

Gatekeeper Process

Structure

Most alternative methods would not fall under the precertification language of indemnity plans. Therefore, the indemnity plan would be examining the efficacy of the alterna-

tive treatment after the patient had already received the treatment. In contrast, managed-care plans, such as HMOs and PPOs arrange all care that cannot be provided by the insurance plan, throughout placement referral. In these plans, the same rules would apply when a patient asks for referral to a specialist. An ethical physician should attempt to create a dialog with the patient which considers and respects the patients interest in the alternative therapy and what the patient needs to know in order to make an informed decision regarding treatment options. The alternativist should do the same regarding the standard medical options. The dialog should cover:

1. What does the patient expect from this approach?
2. What has the patient been led to believe this approach can deliver?
3. How realistic is the achievement of these objectives?
4. What effect will the treatment have on quality of life?

Healthcare plans, depending on size and demand, have been known to establish a mechanism internal to the plan to assess a proposed intervention's effectiveness. In some cases, plans have referred specific questions on particular interventions to consultant organizations with expert systems or expert review panels. Whatever mechanism is employed, the first step in any assessment process, requires the location of the studies producing usable data, the analysis of those studies and, usually, the supplementation of these areas of information by the addition of expert opinion. The end result of this process is usually a procedural statement or guideline to determine whether the treatment is covered and, if so, the characteristics of the patient who can expect to benefit from it. An additional step by most plans, particularly when the member has a terminal illness, is referral out for external review before making final coverage decisions *(8)*.

Medical-consensus acceptance and in some cases, organized clinical data, although to some degree controversial, provide a basis for coverage of appropriate chiropractic, acupuncture, pain

control techniques, mind–body relaxation techniques, homeopathic medicine; and well-credentialed nutritional interventions. This level of acceptance/support of the proper application of these therapies supports labeling as standard medical care and not as "alternative." For other "alternatives," there is little organized clinical data from adequate studies that would permit evidence-based conclusions to be drawn about the benefits of their interventions. The absence of this information provides a serious dilemma for health care plans. A health plan that sets a precedent for paying for procedures that may be ineffective, and are considered unproven, has set itself up to be forced, through litigation, to pay for any treatment demanded, regardless of its provenance. This result is mandated by the even-handed interpretation and application of like principles in the claims-evaluation process when specific named exclusions are not set forth.

An initiative by Oxford Health Plans employs an approach to alternative therapies that is not constrained by evidential based tests, using instead patient preference and providing access apart from the basic-benefits plan, and employing a provider credentialing/expert-panel approach. Commencing in January 1997, Oxford began offering members access to specified alternative services through a supplemental rider, or members can opt to use a provider from physicians credentialed by Oxford and pay a negotiated rate themselves. The offering is based on a survey of their members that disclosed that about one-third were visiting alternative medical providers. The authors have no knowledge of the survey structure. However, responses should be carefully scrutinized and placed in cultural perspective. The service area of Oxford is rich in diverse cultures that may have imported their Eastern or traditional medical healers into this country. It would be informative to know how many of the visits were to traditional cultural "healers" *(50)* and how usage is impacted by the increasing cultural diversity of the population in the Oxford service area *(51)*.

Oxford providers will include acupuncturists, massage therapists, chiropractors, registered dietitians, clinical nutritionists,

and yoga instructors, as well as diet and nutrition counselors (masters-level registered dieticians with training licensed by the state), and nutritional counselors (with at least a master's-level degree in clinical nutrition from an accredited university)—most of these will be Ph.D-level nutritionists. In Connecticut, the network will also include naturopaths (not currently licensed in New York or New Jersey), the two other states where Oxford operates health-maintenance organizations. In using the rider or fee-for-service approaches, it is possible that Oxford may escape the dilemma of having to pay for all therapies of any description regardless of their evidential basis. This peer-evaluation approach is extra contractual to the basic benefits package and can have its own rules for application *(52a)*.

The Oxford process is that core providers will see an Oxford member and they will be provided an opportunity to submit a care plan to an expert. The care plan will be reviewed by an expert among the core providers in place (peer-review panel coming from the community of local practitioners), who will review the care plan and develop a level of comfort about what is happening. The expert(s) may then approve a certain strategy or approach or amount of care, etc. based on the standards of practice in that community and the scope of licensing in the state of the practitioner. Oxford avoids endorsing treatments by inclusion in their core care package and defers decisional authority to credentialed providers and expert panels *(8)*.

Alternative-medicine providers participating in Oxford's network must meet credentialing standards developed by three advisory boards, one each for chiropractors, acupuncturists, and naturopaths. Providers must be licensed in the state in which they practice, have graduated from a fully accredited college, demonstrate two years of continuous clinical experience, pursue continuing education, and carry proper malpractice insurance.

A healthcare plan may decide to offer "popular" therapies. Consumers indicating choices are acting on the belief that there are painless, and sometimes inexpensive and effective remedies for what ails them. Does the patients' right to choose remove the

responsibility of a managed-care program to employ its own gatekeeper approach at least to be sure that the member is aware that the treatment approach has not been demonstrated by an objective system of proofs to be effective for their particular condition, and that there are other treatments, when applicable, that have been so demonstrated? Should the managed care program be particularly aware of the way that treatments are presented to patients so that the informed-consent process is not more akin to an infomercial than what should be expected in an ethical patient/physician dialogue? The parallels to the period in which laetrile was legalized by the states without objective proof of benefit are compelling *(17)*.

Resources for Evidential-Based Information and Standards

The United States Pharmacopeia (USP) Convention is recognized by federal legislation as the resource for drug standards. In addition, its information division's program, Drug Information for Physicians, is an authoritative resource used by healthcare plans to determine labeled and scientifically supported off-label uses (not on FDA approved labeling). USP has expanded this activity to standards and information on vitamins, minerals and dietary supplements and is, at present, considering expansion into standards and information on botanical products. The USP, through volunteer panels of over 1200 medical and scientific experts, has an established track record for objective and scientifically accurate standards and information. The USP could be the ideal system to furnish the same categories of information to meet the needs of the payor and consumer public for making informed health care choices in alternative therapies. The USP system is objective, free of conflict of interest, and has established its ability to provide comprehensive coverage. The USP does not undertake standard or information development on products that have not established efficacy in some area *(52)*. Inclusion in the USP would thereby satisfy the evidential requirements

of payors for coverage, i.e., that the included products have recognized medical or dietary uses that are supported by adequate evidence and whether their identity, strength, quality, and purity can be adequately standardized *(53)*. In addition, the expert drug and supplement systems already in place would facilitate development of crucial information on multiple dosing, and interactions among foods, drugs and supplements *(54)* that could allay the "safety" concerns of health plans examining the risks of coverage and vicarious liability. Finally, on August 1, 1997, following board direction, the USP has:

> modified the admission criteria for determining how monographs for drug and other health care related articles will be included and made available in the *United States Pharmacopeia (USP)* or *National Formulary (NF)* compendia. In the future, monographs for articles with either a USP DI accepted use, or ones approved by the Food and Drug Administration (FDA) will be published in the *USP*. Monographs for articles that are not FDA approved or for which there is no USP DI accepted use, that are used extensively, and for which, in USP's judgment, there is no significant safety risk, will be published in the *NF*. The newly adopted policy also states that no monograph will be established in either compendium when there is a significant safety concern. When such a significant safety risk is associated with an article, however, a *negative* monograph may be published in USP's compendium of drug, nutritional and therapeutic information, the *USP DI®*.

For more information, contact Jacqueline L. Eng:jle@usp.org, 301-816-8230.

Conclusion

Gatekeeping is essential to assure that premium dollars are not wasted on ineffective care. The development of relevant evidence based systems to establish the outcomes related benefit of

alternative therapies will open up coverage. The gatekeeping function will be an essential part of healthcare plans' functioning until a formal education process has produced a generation of informed medical consumers ready and able to understand and critically evaluate their own medical care options. This process must provide complete, truthful, and verifiable information regarding the benefits that can be expected from all treatment options. Only then will the medical consumer be sufficiently informed to make the most appropriate health care choices.

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Abstract

Overall, few Americans have insurance coverage for complementary and alternative medicine (CAM). Notable health plans that do offer coverage are presented. In order for CAM to achieve coverage levels on a par with conventional treatments, the integration of CAM and conventional medicine is essential.

Challenges that must be overcome to achieve integration include medical-licensing laws that effectively limit the practice of CAM; the viability of CAM fitting into the prevailing reimbursement structures that are based on identifiable disease states and procedures, not holistic theories and practices; quantifying the cost benefits of CAM; the lack of communication between the CAM and conventional-medical communities; and skepticism manifested by CAM proponents' charges of economic protectionism on the part of the conventional medical community and counter-charges by the conventional medical community that CAM is quackery. Agreement on whether CAM is quackery or safe and efficacious is, in fact, the most significant barrier to integration and is the overarching issue influencing both healthcare practice and policy in this area.

The extent to which expanded insurance coverage for CAM is good health policy is also discussed. Issues examined include balancing a patient's right to choose his or her healthcare treatment with the state's exercise of its police power to protect the public welfare; the ethics of mandating or supporting CAM coverage via increased health premiums, when many subscribers view it as quackery; and whether rationing should be considered if one assumes that expanding coverage for CAM would saturate an already overloaded healthcare system.

A new paradigm of healthcare delivery is urged. This paradigm integrates CAM and conventional medical practice; ensures access to both treatment modalities; contains healthcare costs but balances the benefits and downsides of the fee-for-service and capitated reimbursement systems; and is a holistic, patient-centered approach to health and wellness.

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Insurance Coverage for Complementary and Alternative Medicine

Access, Challenges, and Policy

S. Mitchell Weitzman, J.D., LL.M.

Introduction

The explosion of interest in complementary and alternative medicine (CAM) is apparent in many ways. Articles appear almost daily in newspapers and magazines. Programs on radio and television frequently discuss CAM treatment. Walk into many pharmacies today and one is likely to see nearly as many herbal and homeopathic products as traditional pharmaceuticals *(1)*.

At least in terms of media attention, the explosion of interest in CAM can be traced back to an often cited 1993 study in the *New England Journal of Medicine (2)*, which reported that nearly a third of all Americans were visiting alternative health practitioners and spending some $13.7 billion out-of-pocket for services not covered by their health plans. Among other groups, this study caught the attention of many health plan administrators,

who began to see a potentially lucrative market largely untapped by traditional health-insurance offerings.

The growth of CAM is evidenced by:

1. The creation in 1991 of the Office of Alternative Medicine (OAM) at the National Institutes of Health (NIH) *(3)* to fund research on CAM therapies;
2. The launch of scientific journals dealing with CAM *(4)*;
3. The introduction of CAM courses taught at 34 of the country's 125 medical schools *(5)*;
4. The passage of a revolutionary coverage law in Washington state in 1995 *(6)*;
5. The introduction of the Access to Medical Treatment Act in 1996; and
6. The comprehensive coverage of CAM treatment by more than a dozen health plans *(7)*.

Alternative therapies have been the standards-of-care in other cultures for centuries *(8)*. Until the early 1900s, some of these therapies were prevalent in the United States, too. Yet the successes of disease-based Western medicine—between 1900 and 1990, the life-span of whites increased by one-third, whereas nonwhites doubled their life expectancy—led to the virtual disappearance of CAM until recently *(9)*.

Why the attraction of CAM? Frustration with the limitations of conventional medicine is one reason. Various studies have indicated that from one-half to two-thirds of patients who visit a primary care provider for a health problem are mainly suffering from psychosocial stress manifested as a physical complaint, such as chronic backaches, fatigue, and high blood pressure. However, few medical doctors are trained in recognizing and managing stress-related health problems *(10)* and fewer still manage to spend more time with a patient than a 10-minute office visit *(11)*.

This chapter presents the current state of insurance coverage for CAM and discusses policy issues that affect its inclusion in the healthcare delivery system from both a medical delivery and

insurance perspective. The following section defines CAM and presents a brief glossary of key treatments. The third section reviews overall insurance availability for CAM coverage, including specific coverage policies of nine notable health plans, and the fourth section discusses barriers to accessing CAM—such as utilization review (UR) and medical licensing laws—within the context of insurance coverage. The fifth section presents challenges in the integration of CAM and conventional medicine from both the medical practice and insurance perspectives, including the debate over the cost-effectiveness and clinical efficacy of CAM. The last section discusses whether integration is ethically appropriate, particularly whether it is good health policy. This section examines the arguments that can be made about the patient's right to choose his or her treatment, the role of government regulation, the appropriateness of mandating CAM coverage, and whether cost containment and rationing should be considered in determining how expansive coverage for CAM should be.

Defining Complementary and Alternative Medicine

CAM has been subject to many different definitions and interpretations. Defining CAM is important for a number of reasons. First, a review of these variances illuminates the value impressions that exist toward CAM. Second, definitions become particularly important in insurance contracts. Relatedly, if CAM is to be integrated with conventional medicine as part of the healthcare-services continuum and achieve similar levels of insurance coverage, it will become increasingly important for the CAM community to define itself more clearly.

Robert Padgug, former Director of Health Policies and Government Relations at Empire Blue Cross Blue Shield (NY), describes CAM as a wide variety of treatment modalities that do not equally coexist, are based on different theoretical and practi-

cal approaches and attitudes to the body and its ills, are derived from divergent cultures, and have widely varying rates of utilization and success. What approach, he asks, can reconcile in a single intelligible grouping such disparate phenomena as Chinese acupuncture, chiropractic, homeopathy, biofeedback, crystals, and herbalism? Padgug thus prefers to term CAM a "catchall' phrase and defines it by what it is not—approaches and therapies that are opposed to or remain outside of Western medicine *(12)*.

David Eisenberg et al. *(2)* also define CAM by what it is not, i.e., "medical interventions not taught widely in U.S. medical schools or not generally available in U.S. hospitals." Even the OAM defines CAM as any medical practice that is generally not taught in medical schools, is not documented in the United States for efficacy and safety, and is not reimbursed by third-party insurance *(13)*. The American Medical Association (AMA) Vice President for Education and Science has simply defined CAM as "unproven remedies" *(14)*.

For purposes of this chapter, I employ the increasingly widely used term "complementary and alternative medicine" to apply to specific treatments, practices, or philosophies, examples of which are described in the glossary. The addition of "complementary" to "alternative" corresponds with the view that these treatment modalities should complement, not compete with, conventional medicine.

Glossary

Acupuncture theory holds that disease is related to imbalances in the body's energy, or qi (pronounced "chee") and that balances can be restored by stimulating certain points on the body surface by inserting needles at specific sites just below the surface of the skin. The insertion points are thought to have deeper links to the body's internal organs.

Ayurveda, practiced in India for more than 5000 years, seeks not only to overcome illness but also to create a strong body, clarity

of mind, and tranquillity of spirit. Ayurvedic practitioners—Deepak Chopra is a prominent example—combine diet, yoga, meditation, and natural substances to achieve balance and health.

Biofeedback provides visual or auditory evidence of the status of certain body functions as a means of exerting voluntary control over those functions to alleviate an abnormal condition.

Chiropractic practitioners believe that past physical, emotional, and chemical traumas cause interference with the nervous system which must be adjusted to align the spine and nervous system, allowing the body to heal from within.

Homeopathy works on the theory that the immune system can be stimulated to fight illness by administering an extremely diluted dose of an herb, mineral, or animal substance that would cause the same symptoms in a healthy person. For example, someone with rheumatoid arthritis would take a minute amount of a substance that would induce arthritic symptoms in a healthy person.

Massage therapy involves the manipulation of the superficial or deep tissue, muscle, or connective tissue by applying pressure to the hands, feet, arms, or elbows, improving mobilization and relieving stress and muscle tension.

Naturopathy is a system of prevention, diagnosis, and treatment of health conditions and diseases that uses natural medicines and therapies to stimulate an individual's self-healing processes.

How Health Plans Cover Complementary and Alternative Medicine

Until recently, most Americans interested in CAM therapies paid for the cost of treatment themselves. In 1990, for example, only $2.4 billion of the estimated $12.7 billion spent on CAM was covered by insurance *(15)*. Although the coverage environment has grown dramatically since then, for most Americans insur-ance coverage for CAM therapies other than chiropractic

care is the exception and not the rule. Insurers are more likely to reimburse approaches to disease that cure, rather than care; that focus on the body, rather than the spirit; and that are supported by stud-ies in prestigious American medical journals, rather than on studies that do not meet the scientific "gold standard." *(16)*. (*See* discussion on Documenting Clinical Efficacy.)

A discussion of health plan coverage must begin with employers, because they are the primary purchasers of health insurance via employee health benefits. It is employers who for the most part ultimately determine what benefits will be available to employees. According to a 1996 *Business & Health* survey, only 7% of small firms and 8% of large firms purchased CAM (excluding chiropractic) as part of their employee benefit package. Interestingly, chiropractic treatment was purchased by 60% of employers *(17)*. Statistics on coverage in self-funded plans were not available, but are likely to be similar to those applicable to non-self-funded plans.

Thus, most Americans still generally do not have health- insurance coverage for CAM therapies other than chiropractic care. One might expect, however, that the impetus for broader insurance coverage to include CAM will come from employers, who over the last few years have established "worksite wellness" and "health promotion" programs. Studies have shown that these programs reduced absences, increased health, and saved the employer money *(18)*.

Table 1 highlights notable health plans covering CAM. Aspects of these plans that affect patient access to CAM treatment, integration with conventional medicine, and broader policy-making decisions are discussed throughout the remainder of this chapter.

As previously noted, chiropractic care enjoys the most comprehensive insurance coverage, followed by acupuncture *(19)*. In fact, at least 41 states require private health insurers to cover chiropractic care and six require acupuncture coverage *(20)*.

Barriers To Accessing Complementary and Alternative Medicine

This section addresses barriers that can inhibit access to CAM treatment. Barriers include limitations on covered benefits, UR, and medical-licensing laws that regulate the practice of medicine and practice guidelines. The lack of integration of conventional medicine and CAM, both in terms of medical practice and health-insurance schemes, can also inhibit access to CAM. Under that heading, the next section discusses the need to come to terms on the cost effectiveness of CAM as well as documentation of its efficacy. Successful resolution of these issues will be crucial if most barriers to accessing CAM are to be eliminated.

Benefit Limitations

As indicated in Table 1, even the most progressive health plans impose limitations on what CAM therapies it will cover, as well as dollar caps on covered benefits. Some therapies, such as energy healing, are considered more "alternative" than others, and are not covered. Other, more "accepted" therapies, such as acupuncture or chiropractic, are covered by some plans only for specified indications, such as substance abuse and lower back pain, respectively. Plans admit that they still have a lot to learn about making CAM coverage decisions, noting that it is a challenging and evolving process.

Coverage policy limitations, therefore, are varied, and occasionally curious. Some examples:

- American Western does not cover energy healing; does cover hair analysis ordered by naturopaths.
- Blue Cross of Washington and Alaska does not cover hair analysis as medically necessary; limits massage therapy to the same rehabilitation condition requiring physical therapy; and does not yet cover herbal remedies.
- Kaiser Permanente's Alternative Medicine Clinic covers acupuncture for lower back pain only.

Table 1
Overview of Insurance Coverage for CAM *(21)*

Name of plan	Benefits	Comments
Blue Cross of Washington and Alaska	Covers all CAM treatment as required by WA state law *(22)* up to $500; subscribers have a 50% copay. (Cap and co-pay are scheduled to be eliminated in 1997.)	Network of 400 CAM providers. Indemnity plans are self-referred; managed-care plans deem CAM providers as specialists requiring referrals from a primary care physician
Alternare of WA, Inc.	Offers MyChoice, a prepaid healthcare program using a debit card. Subscribers go to network providers	Also contracts with several health plans for provider credentialing, billing, and coverage consulting.
American Western Life (Midwest, West)	Generally covers up to $300/year for acupuncture, spinal treatments, and so forth.	Plans are sold primarily to individuals and families. Subscribers have access to a 24-hour holistic hotline.
Alternative Health Benefit Services	Covers up to $1000 for chiropractic and acupuncture; up to 25 massage therapy sessions/year at $25/session; homeopathic/herbal remedies up to $500/year.	Negotiates and develops CAM plans underwritten by other companies.

Kaiser Rehabilitation Center (Vallejo, CA)	Alternative Medicine Clinic offers treatment for chronic pain, including relaxation training, nutritional counseling, and acupressure.	Two-hour class called SMASH (self-massage acupressure for self-healing) also in cluded in benefits package; PCP referral required.
Oxford Health Plans (CT, NY, NJ)	Acupuncture, massage therapy, chiropractic, naturopathic (only licensed in CT).	Plan has four components: a credential network of CAM providers accessible to plan subscribers; a benefit plan that can be purchased as a supplement; mail-order service for vitamins, remedies; and an information service. Patient can self-refer. CAM provider must submit a care plan.
HealthPartners Health Plans (AZ)	Covers acupuncture, guided imagery. Chiropractic requires a separate rider. Herbs covered, but not as an alternative to prescription drugs. Massage therapy, naturopathy not covered.	Patients can self-refer to a CAM provider once a year after a complete health assess ment by a physician.
Group Health Cooperative (Seattle, WA)	Chiropractic, massage therapy (only if medically necessary), acupuncture, naturopathy.	Referral by a primary care physician; CAM providers must submit treatment plans and progress summaries.
Mutual of Omaha	Covers Dr. Dean Ornish's program for reversing heart disease (using diet, meditation, and exercise) under its major medical policy.	Currently conducting outcomes studies.

- Oxford considers nutritional counseling CAM yet does not cover it. Considering the increasingly well-documented relationship between nutrition and health, one wonders whether this coverage policy makes sense, both medically and economically *(23)*.

Finally, benefits can sometimes be limited or denied if an insurer views a patient's therapy as falling within an "experimental treatment" exclusion. Yet experimental treatments differ from CAM in that experimental treatments involve procedures designed to test a hypothesis (such as organ transplants), whereas CAM treatments typically are preventive or oriented toward overall health. One court in the Fifth Circuit, ruling on an acupuncture coverage issue, stated it best: "What is experimental is not acupuncture, but Westerners' understanding of it" *(24)*.

Utilization Review

UR is a process by which a plan determines whether a given procedure or set of services is covered, and by which it handles any technical review and appeals. UR can be prospective, concurrent, or retrospective, and is a means of both containing costs and assuring quality care.

In the context of CAM, UR as a barrier to access within the larger health insurance system (i.e., not those enrolled in cutting edge plans as described in Table 1) is examined first, followed by a discussion of the nature of UR within plans listed in Table 1.

UR and "Conventional Benefit Plans"

Most people who want access to CAM treatments will come face to face with the UR process when prior authorization is not granted or their claim is denied for their acupuncture treatment, naturopathic consultation, or any CAM therapy. These denials will most often be based on lack of coverage, or for lack of "medical necessity." Demonstrating medical necessity can be a particularly vexing problem in terms of CAM coverage. Medically necessary treatments are typically defined as those treatments

that are "reasonably intended, in the exercise of good medical practice, for the treatment of illness or injury" *(25)*. The term itself reflects a bias toward conventional medical practice, indicating that any particular procedure or treatment must have scientifically provable efficacy *(26)*. Thus, most health plans do not acknowledge that necessity also depends on non-medical health professionals and treatment.

In a study for the American Association of Naturopathic Physicians, consultant John Weeks notes that answering to skeptical UR committees poses a "core challenge for the naturopathic profession" *(27)*. For example, a UR panel is likely to question what added value can be demonstrated by a typical naturopathic patient intake, which can last nearly two hours longer than that by a conventional physician.

UR in "CAM Inclusive" Benefit Plans

In those health plans that do offer CAM benefits, UR has not been a significant barrier to access. The extent of UR in most plans—particularly managed care plans—is the requirement that subscribers get a referral from their primary-care physician in order to receive CAM treatment.

Oxford does not require referral by a gatekeeper, but does require CAM providers to submit a care plan. Richard Winner, Vice President of Marketing of Blue Cross of Washington and Alaska, said there is no separate UR plan for their CAM program, adding that what is done now is "ad hoc." Other plans said they employed "standard UR procedures." Darryl Stewart of Alternare described the questioning of a massage therapist who was treating patients for one and a half-hours, when a half hour was standard as an example of their UR activity.

To the extent that UR programs are in place at these plans, how are procedures reviewed, or, more specifically, by whom? One way a UR process can effectively restrict access to its subscribers is if its reviewers were conventional medical practitioners, either unknowledgeable about or biased against

CAM. Interestingly, the National Committee for Quality Assurance (NCQA), an accrediting body for managed care plans, does not address this issue in its practice standards related to UR *(28)*.

The plans listed in Table 1 allay these access fears. They generally indicated that UR would be performed by peers in the particular CAM discipline.

Medical-Licensing Laws

One of the barriers in accessing CAM treatment has been medical licensing laws that prohibit the unauthorized practice of medicine. Each state licenses medical doctors and defines the "practice of medicine." These laws generally define practice of medicine broadly *(29)* and then make it a crime for anyone other than a licensed physician to undertake those activities. Regulatory schemes are aimed at protecting the public from the dangers of unskilled practitioners and unsound treatment or advice *(30)*. A more cynical view is that barriers to access have been erected owing in large part to the pressures from the conventional medicine community trying to protect their own turf. Physician groups have tried to eliminate the practice of various CAM providers, including chiropractors *(31)*, homeopaths, and naturopaths.

Until recently, therefore, the regulatory scheme has clearly favored a healthcare system dominated by conventional medicine, inhibiting patient access to CAM treatment. For example, Oxford Health Plans, one of the most comprehensive health plans available, does not offer naturopathy benefits in New York and New Jersey because naturopaths cannot get licensed there.

Proponents of CAM have advocated limiting the definitions of practice of medicine and ensuring that CAM providers acting within the scope of their own practice should not be considered to be practicing medicine without a license *(32)*. Indeed, the regulatory environment for CAM practitioners has become significantly more favorable *(33)* in terms of recognizing licensure (and thus legitimacy for many insurers) of CAM practitioners and treatments, as indicated by Table 2.

Table 2
State Licensure of CAM

CAM treatment	Number of states licensing
Chiropractic	51
Massage therapy	25
Naturopathy	12
Acupuncture	28

Practice Guidelines

Many physicians decry the use of practice guidelines as "cookbook medicine." Yet its development and growth for many disease states is simply a matter of time, even for CAM therapies *(34)*.

The extent to which CAM treatments are included in those guidelines will likely have a profound effect on patient access *(35)*. Much depends on the success of integrating conventional medicine and CAM, particularly with regard to agreement on documenting efficacy. The following discussion addresses this issue in detail.

Integrating CAM and Conventional Medicine

The previous section discussed barriers to patient access of CAM treatment. The lack of clinical as well as economic (i.e., insurance) integration between CAM and conventional medicine can often limit patient access to the range of healthcare therapies available. Challenges in integrating CAM and conventional medicine are presented in this section. These include determining the cost effectiveness of CAM, documenting its safety and efficacy, the ability of CAM providers and treatments to fit into the prevailing reimbursement structures, and the lack of communication and trust between the CAM and conventional medical communities.

Cost Effectiveness

The extent to which CAM is deemed to be cost effective will have a major impact on its success in integrating into conventional medicine coverage schemes. Indeed, lower cost of treatment is often CAM's major selling point.

Dr. Paul Wolpe of the University of Pennsylvania Center for Bioethics notes that managed care organizations are "schizophrenic" when it comes to covering CAM. Though they often view it as a lower cost treatment alternative, they fear they may be "opening Pandora's box" with, for example, patient demands for massage therapy once a week. Dr. Marco Zollezzi of Kaiser Permanente's Alternative Medicine Clinic echoed these sentiments: "I haven't determined whether CAM is cost effective, but patients seem to be satisfied. Yet I don't want to turn the clinic into a massage parlor."

One of the most widely cited examples of cost effectiveness is the Reversal Program for heart disease, covered by Mutual of Omaha. It is a prevention and behavior modification program popularized by Dr. Dean Ornish to reduce the risk of heart disease through yoga, meditation, diet, and support groups instead of surgery or medication. The program costs $4,000 per person, whereas bypass surgery on average costs $43,000 and angioplasty costs $18,000 *(36)*. Mutual of Omaha estimates that it saved $6.50 for every dollar it invested in the program *(37)*.

Although examples of the cost effectiveness of CAM have been documented, many plans, such as Blue Cross of Washington and Alaska, were unsure whether CAM would ultimately prove to be cost effective. Others, such as American Western, are actively gathering cost-effectiveness data. Mary Fedek, Director of Provider Relations, "feels strong" about CAM's potential in this area.

Some in the insurance industry worry that coverage of CAM will lead to patients' use of both CAM and conventional treatments, saturating an already overloaded healthcare system and driv-

ing up costs. A Nationwide Insurance representative has been quoted as saying, "We have an obligation not to say 'yes' to everything." Robert Padgug, formerly of Empire Blue Cross Blue Shield, maintains that CAM costs are additive, not substitutive *(38)*.

Blue Cross of Washington and Alaska's early experience lent credence to Robert Padgug's concerns. The first insurer to attempt CAM coverage via its pilot AlternaPath plan, 1,000 subscribers paid $171 to cover up to $1000 in CAM benefits. Demand for that program exceeded expectations. "We couldn't cover the cost with the premium we charged," said Richard Winner. However, utilization for its now permanent program has been lower than expected. Darryl Stewart, President of Alternare, attributes the low utilization of many of the plans they administer to a lack of knowledge on the part of patients and lack of referrals by physicians.

Lee Launer, a partner with the accounting firm Coopers & Lybrand, has been leading the effort to quantify some of the benefits of CAM. He is attempting to answer the question of whether it makes sense for insurance companies to cover CAM. Among the endpoints he is analyzing are mortality, missing work days, and hospital length of stays. The goal, he says, will be to take alternative therapies out of the anecdotal mode and into a factual framework *(39)*.

Documenting Clinical Efficacy

Perhaps the single most divisive issue impeding the integration of conventional medicine and CAM, and thus also impeding a level playing field in terms of insurance coverage, is the extent to which efficacy for CAM can be demonstrated and what standard should be applied. On this point, mistrust, lack of communication, and fundamental philosophical differences between the CAM and conventional-medicine communities prevail.

"Alternative methods are woefully deficient in clinical and cost outcomes," notes Kenneth R. Pelletier, Ph.D., Clinical

Associate Professor at Stanford University School of Medicine and Director of the Stanford Health Program *(40)*. William T. Jarvis, Ph.D., Professor of Public Health and Preventive Medicine at Loma Linda (CA) University School of Medicine and President of the National Council Against Health Fraud, takes issue with the fact that by virtue of its reliance on clinical trials, conventional medicine is open to and publishes its failures as well as its successes, whereas CAM offers only "anecdotal reports as evidence of its safety and efficacy" *(41)*. Robert Padgug highlights the essence of the different approaches: "What is normally tested in the medical model is particular procedures and treatments, not entire philosophies or approaches to the human mind and body" *(42)*.

As a physician and CAM practitioner, Dr. James Gordon, author of *Manifesto for a New Medicine* and Director of the Center for Mind-Body Medicine in Washington, DC, is in a position to evaluate both sides of the controversy: "Research is not a pure enterprise," he states. "What is valued and accepted as truth at one time and place depends on many factors, including the prevailing world view and economic interests of those who define truth and control the research enterprise that produces it" *(43)*. His description of the clinical trial process and its flaws follow.

Currently, the randomized control trial (RCT) is the clinical research design of choice. This is a procedure in which research subjects matched for similar disease states and demographic characteristics are randomly assigned to two or more groups; one group receives the "intervention" (e.g., drugs, surgery) and the other "untreated" group serves as the "control." Pharmaceutical clinical trial patients are often given a placebo so that they too believe they are being treated. The results of the study are "significant" if the treated group on the average does markedly better (as determined by statistical procedures) than the control group. Wherever possible, those who administer the treatment and those who evaluate the results are "blinded;" that is, they are unaware of which people have received treatment and which have not.

Because of its utility and quantifiable results, RCTs have become the "gold standard" of clinical research.

Why haven't CAM treatments generally been subject to RCTs? There are several reasons. First, although this approach is useful in drug trials, it has limitations when it comes to many therapies, both conventional (like surgery) and alternative. It would be inappropriate for a surgeon to be "blinded" in what he is doing; similar problems arise with hands-on healing techniques like acupuncture and chiropractic. Second, RCTs are expensive, requiring resources on a par with pharmaceutical manufacturers. Third, there is little financial incentive to launch RCTs on substances that cannot be patented, like herbs, vitamins, or homeopathic remedies *(44)*. Finally, Dr. Larry Dossey, Executive Editor of *Alternative Therapies in Health and Medicine*, states that RCTs may be inappropriate for many CAM treatments because, among other reasons, their action is affected by factors that cannot be specified, quantified, and controlled. For instance, many alter-native practitioners commonly refer to spiritual factors as determinants in therapy. Concepts such as qi, chakras, energy patterns, and healing vibrations are often employed by CAM practitioners *(45)*. In summary, CAM proponents believe that RCTs work best for interventions with easily definable disease states, not where the complexity and uniqueness of the individual are ignored in favor of statistically averaged outcomes.

CAM treatments that have been studied for efficacy, but not via RCTs, have been largely ignored or dismissed by conventional medicine *(46)*. Although these studies frequently appear in respected foreign medical journals, they rarely appear in American medical journals.

James Gordon and other CAM proponents assert that it's not a matter of discarding the RCT, but of respecting and using other methodologies as well *(47)*. He identifies the need to scientifically address the questions of "energy medicine." Larry Dossey says that "something needs to be added to the laws of physics and chemistry before certain biological phenomenon can be understood

completely. That something is related to the mysteries of consciousness, which in orthodox medicine has not yet found a home" *(48)*.

Recognizing the need for additional research, OAM in 1996 awarded $9.6 million in grants to 10 Alternative Medicine Centers to study addictions, aging, asthma, allergy and immunology, cancer, general medical conditions, HIV/AIDS, pain, stroke and neurological conditions, and women's health *(49)*. Definitive outcomes results are, however, a long way off, even acknowledged within the CAM community. For example, at a recent meeting on the "physiology of acupuncture" sponsored by the American Academy of Medical Acupuncture, no consensus emerged about the way acupuncture works on the human body or about its effectiveness compared to other treatments *(50)*.

Medical-Licensing Laws

As previously discussed, medical licensing laws, by virtue of their historical bias toward conventional medicine, can also negatively affect integration. Licensure is a critical component of credentialing, a prerequisite for many conventional and CAM providers contracting with health plans. Regulatory schemes that fail to acknowledge a role for CAM providers thus impede integration, and, ultimately patient access to a full range of healthcare choices.

Reimbursement

The ability to "fit" into the existing health insurance reimbursement structure is also a major challenge in terms of integration. That structure is based on the conventional medical model which emphasizes diagnosing particular illnesses and diseases and recommending procedures to alleviate those conditions. It is not holistic. There are no billing codes, for example, to treat stress-related conditions with guided imagery.

Margaret Colgate, who studied the mechanisms by which chiropractic care and acupuncture gained credibility and thus a

better reimbursement profile, cites three criteria for CAM reimbursement success *(51)*:

1. The ability to fit into the existing diagnosis based system.
2. The willingness to be viewed as complementary, and not competing, therapy.
3. The willingness to follow the generally accepted biomedical model of professionalism by providing education standards and accreditation, professional licensure, and documented clinical-practice guidelines.

Chiropractic was not only able to meet these criteria, says Colgate, it also targeted the niche of lower back pain for which conventional medicine had no equally effective or attractive alternative. Acupuncture, meanwhile, has also become a niche coverage area for acute pain and detoxification, though it has achieved less coverage success than chiropractic, likely because it is more problematic to evaluate than chiropractic. The philosophy of acupuncture represents a unique treatment for each problem, negating the utility of practice guidelines, or even basic consensus on outcomes, as previously discussed.

Reimbursement tools, such as coding and fee structures remain a problem for most CAM treatments. Few Current Procedural Terminology (CPT) codes (maintained by the AMA) are available *(52)*. Most CAM providers are reimbursed based on time, creating its own reimbursement challenges. For example, naturopaths typically spend up to two hours with a new patient, compared to conventional physicians, who typically spend no more than one hour. Alternare is currently examining that particular issue for several of its health plan clients.

James Gordon's belief that providers should be reimbursed for the time they spend with patients, not for the particular procedures they perform on patients, represents the challenges and tensions that Alternare and other plans will face as they attempt to integrate CAM with conventional medicine using the reimbursement tools currently available.

For all the upsides insurance integration might mean for CAM providers—more coverage and more dollars—the downsides are significant as well. Currently, because so much of their care is paid out-of-pocket, they do not have to deal with many of the healthcare realities prevalent today in conventional medicine: capitation, UR, and claims filing hassles *(53)*. Patients, unlike insurers, do not demand to see clinical trial data before procedures are performed.

Finally, CAM providers have largely been immune to malpractice suits. To some extent, this is probably due to the more personal relationships patients establish with their CAM providers. Quite possibly, it is also becuase CAM providers, unaffiliated with large medical institutions or health plans, do not represent the "deep pockets" plaintiffs' attorneys so often seek. Additionally, the lack of malpractice suits could be the result of the lack of standards of care for many CAM treatment modalities.

Standards-of-care in conventional medicine are typically well-defined; thus, a breach of those standards can comprise a convincing litigation strategy. However, just as the standards that apply to conventional medicine for determining treatment efficacy may not apply to CAM, so too may neither the concept of "standard-of-care," nor the development of standards themselves, apply to CAM treatment. The questions that will need to be addressed in this area are challenging indeed. For example, how shall an acupuncturist's treatment be evaluated in a malpractice case? Because the individuality of each patient is stressed, no real "standard" exists. An acupuncturist could also be held liable for misdiagnosis, but because acupuncturists and conventional practitioners see different things in patients, and have different views of wellness, to what standard will he or she be held accountable? Clearly, this area is ripe for further study.

Communication

Probably most overlooked as a means of integration is communication between the CAM and conventional medical com-

munities. At a 1994 medical ethics conference held at the Mount Sinai Medical Center in New York on "Science, Alternative Care, and Third-Party Payers," no one even represented the CAM community *(54)*. Noted one participant of the conference: "Advocates of alternative and conventional medicine have each often produced excellent insights into the shortcomings of the other, yet have utterly failed to appreciate the other's strengths" *(55)*. As was previously noted, there is almost a complete lack of integration in mainstream medical journals.

Part of the problem is mistrust. Conventional medical organizations, like the AMA, view their mission as protecting the public's health, authorizing them to challenge CAM. Proponents of CAM argue that restricting economic competition is as much of a mission for the AMA as protecting the public's health.

Communication barriers also extend to the patient-physician relationship. Perhaps worried about their reactions or sensing their biases, 72% of patients did not inform their physicians of their visits to alternative providers *(56)*.

The health plans interviewed were generally in agreement that their biggest challenge is integrating what CAM providers do with conventional medicine. At the same time, most also emphasized that CAM providers will not be replacements for primary-care physicians. On a continuum, says Mary Fedek of American Western, CAM is least invasive; conventional medicine is most invasive. "But it's all medicine."

Access to CAM: Health Policy

This section examines some of the competing healthcare policy interests that have and will continue to affect the development and integration of CAM and conventional medicine. These include patients' freedom to choose their healthcare treatment, the police power of the state to protect its citizens, the impact of mandating insurance benefits for CAM, and whether expanding insurance coverage for CAM drains finite healthcare resources.

Patient Choice and the Role of Government

To what extent should patient choice dictate the range of both healthcare services and insurance coverage available to them? The following discussion first examines patients' ability to choose their own medical treatment, then considers how the desire to expand choices to include conventional and CAM treatments impact on insurance coverage and costs for everyone.

Governments have a long history of regulating medical practice. In 2200 BCE, Babylon enacted laws that limited doctors' fees and punished them for treatments that injured their patients. Today, state regulation of health practitioners finds authority in the Tenth Amendment to the U.S. Constitution, which provides that powers not expressly delegated to the federal government, nor prohibited by it to the states, are reserved to the states, or to the people. Among these is the "police power," the power to protect the health, safety, and welfare of citizens. This includes the power to control the practice of healthcare through regulatory schemes *(57)*.

Regulatory schemes have therefore reflected a paternalistic notion of healthcare whereby an uninformed public is protected from quackery and their own questionable choices to access alternative treatments. This paternalism was fostered by the conventional medical community. The AMA *Home Medical Encyclopedia*, under its section on alternative medicine, notes that physicians worry about alternative therapies because diagnosing illness requires extensive medical knowledge, without which an underlying remediable but progressive condition could go unrecognized.

If paternalism is the rationale behind government healthcare regulation, when should it yield to individual liberties? Individuals generally have autonomy to seek any conventional medical treatment they wish. Does that autonomy extend to accessing CAM? One might argue that individual autonomy does not extend to harmful or dangerous treatment (for example, the government ban of laetrile cancer therapy). For those who take such a posi-

tion, the question then becomes: Is CAM harmful or dangerous? Is it quackery? To answer that question, one is again confronted with the issue of how to determine the safety and efficacy of CAM treatments. Until there is a meeting of the minds on that issue, it will be difficult to balance government/individual interests in terms of access to CAM.

Some legislators, however, are prepared to take either a bold or premature step, depending on one's viewpoint, in the direction of breaking down access barriers to CAM treatment. In 1996, a significant bill to expand healthcare options, the Access to Medical Treatment Act was introduced in Congress. Although it did not pass, its cosponsors plan to reintroduce the bill this session. The Act would allow health practitioners to administer any medical treatment, including unapproved drugs, devices, foods, or dietary supplements, as long as there is no evidence that the treatment causes harm and the patient is informed about the treatment and its possible side effects *(58)*. The Act would therefore improve access by, for example, allowing providers acting within their licensure to offer patients non-Food and Drug Administration (FDA)-approved treatments in accordance with the Act's disclosure and consumer protection guidelines *(59)*.

As Michael Cohen, Professor of Law at Chapman University School of Law, points out, the Act favors disclosure over medical paternalism and expresses, through the notion of freedom of access, a "largely unrecognized legal right: to maximize the individual's opportunity for healing disease." The Act, he continues, also "shifts the healthcare paradigm where treatments that do not fit in to the conventional scientific mold or may not be verifiable according to conventional criteria may have a legitimate place in healing" *(60)*.

The Act has been criticized by some, including FDA officials *(61)*, as compromising the FDA's ability to, in essence, fulfill its mission to protect the public from harmful treatments. The role of the FDA and patient choices of alternative, "unproven"

remedies has recently come into play in the case of Dr. Stanislaw Burzynski, who is on trial for providing cancer patients with non-FDA-approved treatment. Dr. Burzynski, through his research institute and clinic in Houston, manufactures and distributes antineoplastons, synthetic versions of peptides found in human blood and urine, that he compares to "microswitches that turn off the cancer process." He has attracted both regulatory and medical scrutiny, despite a 1991 National Cancer Institute review that found "evidence of antitumor activity." Only now is an FDA clinical trial underway. In the meantime, Burzynski is a "savior" to hundreds of patients who rally in support of him and in support of "medical freedom and the right of the severely ill to seek whatever treatment they believe can help" *(62)*.

Are treatment choices the business of government? Ideally, government does and should have a role in regulating healthcare, just as it regulates other areas that affect the public welfare, such as the environment or labor. But political and economic realities often distort the regulatory process. For example, as previously discussed, many alternative treatments do not undergo the FDA-approval process because it is exorbitantly expensive. Does that mean it is any less efficacious than an FDA-approved pharmaceutical? Not necessarily. The Access to Medical Treatment Act appears to be a step in the right direction, balancing a patient's right to make their own healthcare-treatment decisions and the government's duty to protect its citizenry from harmful or dangerous therapies.

The Impact of Health-Insurance Coverage

Passage of the Access to Medical Treatment Act would not mean access to the insurance coverage that will help pay for it. If the Act were enacted into law today, many people who might benefit from CAM would be unable to afford such treatment. As previously noted, few Americans have comprehensive health insurance coverage for a wide range of CAM treatments, but that dynamic is changing rapidly. Health plans like Oxford, eager to get a slice of the CAM revenue pie, promote their responsiveness

to popular demand to "make alternative forms of prevention and treatment more accessible."

More health plans will likely follow. One state, Washington, has even mandated insurance coverage of CAM therapies. The growth of health-insurance coverage for CAM raises some broad health-policy questions, particularly in light of the significant doubts about some treatments' efficacy expressed by many in both the conventional medical community and general population. These questions include: To what extent should the general population be required or mandated to support CAM coverage, via increased health premiums, to benefit the minority of "believers?" And to what extent does an expansion of third-party payment for CAM add to already exploding healthcare costs and therefore unethically drain scarce healthcare resources?

Mandated Coverage

Today's model of primarily job-based health-insurance coverage grew out of post-Second World War competition among employers to attract employees via various benefit packages. In addition, the increasing costs of healthcare, due mostly to the successful technological advances of conventional medicine, made healthcare more of an "insurable event." Prior to the 1940s, Americans paid over 90% of their medical expenses out-of-pocket *(63)*.

As an insurable event, the burden of the total cost of healthcare is theoretically spread broadly among the healthy majority and relatively small minority of the sick. This is known as "risk distribution."

If the costs of conventional medical treatments are distributed via various methods by health plans, why shouldn't CAM treatment? Robert Padgug offers one view. He asserts that because third-party payer arrangements are basically social arrangements for the sharing of medical risk, they entail an obligation to the people served to constrain the tendency to expand coverage and ensure that only "useful" medical care is provided and that costs are kept within society's and individuals' ability to pay *(64)*.

In fact, as one would expect, expanded coverage for CAM can mean a plan-wide increase in premiums, depending on how the coverage is offered, e.g., as a rider, or integrated into the primary insurance contract. Oxford noted that they had raised premiums to accommodate their new CAM program. So too, did plans in Washington state, which have been required by state law to cover CAM therapies.

Washington has long been out front in terms of fostering the growth of CAM. In the aggressive health-reform climate that accompanied the ill-fated Clinton plan in 1993, Washington passed a comprehensive health-reform measure, only to be mostly repealed the next year by a Republican legislature. However, a portion of the Health Services Act that addressed access to CAM survived the repeal. (Note that since the time of this writing, the portions of this act identified below have been struck down by the US District Court in Washington. The discussion presented here, therefore, is still relevant from a policy perspective. *See* note *67* for more on the court decision.)

The Act states that "every health plan (offered) after January 1, 1996 shall permit every category of provider to provide health services or care for conditions included in the basic health-plan services to the extent that:

a) The provision of such health services or care is within the healthcare provider's permitted scope of practice.
b) The providers agree to abide by (plan) standards related to: (1) provision, UR, and cost containment of health services; (2) management and administrative procedures; and (3) provision of cost-effective and clinically efficacious services" *(65)*.

In terms of access to CAM treatment, the law is by far the most expansive in the United States, made even more so through its implementation by the state insurance commissioner, Deborah Senn. Responding to "disturbing reports" regarding health plans' effort to dodge the requirements in the new law, Senn issued a bul-

letin notifying insurers that her office planned on interpreting the law broadly, requiring them to expand access to a wide variety of healthcare providers, including CAM providers. The bulletin added that plans may not exclude a category of provider by asserting that the category fails to meet the plan's standards for provision of "cost-effective and clinically efficacious health services" *(66)*.

Insurance carriers, concerned about their costs to comply with this mandate, filed suit questioning whether the state can impose such a mandate without provisions related to cost. The suit was dismissed on procedural grounds, though legal proceedings continue *(67)*.

Costs that insurance carriers incur are, of course, passed onto subscribers. Thus, is it fair to impose additional financial burdens on subscribers for treatments that may not be deemed—in Robert Padgug's term—"useful" by some or many of them? James Gordon has his own interpretation of "useful." For example, he considers heart bypass surgery often unnecessary and not useful. Yet as a subscriber in a health plan, his premiums would reflect the costs of many such expensive medical treatments.

Many would argue that the very structure of health insurance is in need of repair. The basic elements of maintaining health, such as stress reduction, spiritual fulfillment, and nutrition, are not typically "insurable events" and thus do not fit in easily within an insurance scheme *(68)*. Working within the constraints of our present healthcare system, however, the integration of CAM and conventional medicine should be accompanied by an integration of current insurance schemes and the risk diversification basis inherent in them.

Rationing Healthcare Resources

Although paying for CAM was discussed previously in terms of insurance and risk distribution, this section addresses the costs that are added to the healthcare system as a whole. If one subscribes to the notion that healthcare resources are finite, then

the additional resource utilization represented by the growth in CAM means that other healthcare services will be left out.

The concept of rationing healthcare resources has come to the forefront in recent years because of skyrocketing costs that have kept numerous policy-makers and analysts busy for the last two decades. The nature of how health insurance coverage operated for most of the past half century contributed to rising costs and is instructive in assessing the potential impact of how widespread coverage of CAM will impact resource utilization.

The typical insurance reimbursement model prevalent until the recent growth of managed care is known as fee-for-service (FFS). Under that model, physicians would simply bill for any services rendered and they would be reimbursed either at billed charges, or at a "usual and customary" rate, few questions asked. Their patients, meanwhile, typically paid for only a small percentage of their employee healthcare plan premium, had a minimal or no deductible, and a nominal or no copay. In short, neither physicians nor patients had incentive to economize under the FFS system, because the insurer was footing the bill.

Few physicians or patients have that same luxury today. Yet patients who have largely been paying out-of-pocket for CAM treatments increasingly will be reimbursed by their health plan. Because the FFS system is steadily dissipating in favor of a capitated payment system, it is unlikely that CAM utilization will create an escalation in healthcare costs similar to the transition from out-of-pocket payment of conventional medical treatments to insurance coverage. Nevertheless, as CAM begins the challenging road of integration with conventional medicine, it also becomes part of the healthcare cost "crisis" that touches both the government (i.e., Medicare/Medicaid) and private sectors.

Although few would disagree that the plight of the uninsured represents a crisis in healthcare, the question must be asked: Why are escalating costs considered a crisis in healthcare? If nothing is more treasured than our health, why shouldn't we spend as much as necessary to enhance it? *(69)*. Eliminating some of the

practical reasons, such as rooting out waste (administrative, defensive medicine, and so forth), one response is that all spending is inherently a trade-off because we can always spend on something else instead. Arguments can be made that proper housing, education, and environmental conditions are as much contributing factors to good health as medical care and that more resources should be directed there.

One of the great benefits of CAM is that, unlike so much of conventional medicine, its holistic nature encompasses many of these other spending priorities. Patient education and eliciting from patients non-medical related concerns (such as job stress or environmental conditions) integrates CAM treatment with other facets of life. CAM treatment cannot build good housing, or improve city infrastructures—a trade-off must still exist—but we should encourage its integration with conventional medicine, if it can be shown to improve outcomes, and therefore contribute at least one solution to our healthcare crisis.

Conclusion

Few things are more personal than caring for one's own body and soul. Though conventional medicine has had a remarkable record of success this century, physicians themselves recognize that they do not have all the answers. Today's patients, with unparalleled access to information from the media, the Internet, and direct-to-consumer advertising, have also come to believe that their doctor "doesn't always know best." They are demanding to know about alternative treatment options, often after conventional treatment has been unsuccessful. At best, conventional practitioners are reactive to the developments in CAM, responding to patient inquiries. At worst, conventional practitioners maintain a strong bias against CAM and discourage its use. The best of CAM—an approach to patients as a whole physical and spiritual being, not a collection of organs and body parts that need repair—should be integrated into all healthcare practices.

If the integration of conventional and CAM practice is essential in order to expand patients' treatment options and put a new focus on holistic practice, so too is the inclusion of CAM in insurance schemes. Patient access to medical treatment, conventional or CAM, often depends on third-party payment. The insurable "risk" should be distributed just as it is for conventional medical treatment.

At the same time, coverage for CAM under current insurance schemes can suffer from the same restrictions as conventional medicine. Physicians are frustrated with capitation arrangements and utilization-management techniques that second guess their practice patterns and put the insurer between them and their patient. Patients are frustrated with gatekeepers who can limit treatment options, and with office visits that resemble the Indianapolis 500, with physicians racing from one patient to the next to make up in volume what they lost in fees as capitation/fee schedules replaced FFS.

A new paradigm of healthcare delivery is necessary as we approach the end of the century, one that integrates CAM and conventional medical practice, ensures access to both treatment modalities, and contains healthcare costs but balances the benefits and downsides of FFS and managed care. The new paradigm of healthcare delivery should be a holistic, patient-centered approach to health and wellness. How that new paradigm can be developed is beyond the scope of this chapter. However, the challenges inherent in its development have been presented here and can perhaps serve as a good starting point.

Notes and References

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2. Eisenberg, D. M. et al. (1993) Unconventional medicine in the United States: prevalence, costs, and patterns of use. *N. Engl. J.*

Med. **328(4),** 246–248. In the study, CAM is defined as "medical interventions not taught widely in U.S. medical schools or not generally available in U.S. hospitals." The therapies surveyed, in order of utilization, include relaxation techniques, chiropractic, massage, imagery biofeedback and hypnosis, spiritual and energy healing, homeopathy, and acupuncture.

3. The office is being renamed the Office of Complementary and Alternative Medicine. The change is not yet effective as of February 1997.
4. These include the *Journal of Alternative and Complementary Medicine* and *Alternative Therapies in Health and Medicine.*
5. Neimark, J. (1997) The road less traveled. *Psychol. Today,* January/February, 53, 53–68.
6. The Health Services Act of 1993, Wash. Rev. Code 48.43.045 (1996).
7. Other developments in the last five years were described in "Successful Strategies for Obtaining Reimbursement," presentation by Michael S. Evers, J.D., at the Second Annual International Congress on Alternative and Complementary Medicine, June 10-12, 1996.
8. Worldwide, 70–90% of healthcare uses self-care or care based on an alternative tradition or practice; only 10–30% is based on biomedicine. (*See* note 14, infra,105.)
9. Edelson, M. (1996) Can the New Medicine Cure You? *Washingtonian*, February, 70.
10. Brody, J. (1996) Personal Health. New York Times, November 13.
11. My own experience with allergy and asthma treatment bear this out. My allergist has never made a reference to stress or asked about what in my life could be triggering my current symptoms. I barely begin to speak to him when his prescription pad is out and prepared to prescribe a generous dose of various nasal and chest inhalers. Invariably, I walk out of the office armed for the pharmacy but frustrated and dissatisfied with the visit.
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20. Andrews, L. (1996) The shadow healthcare system: regulation of alternative healthcare providers. *Houston L. Rev.* **32(5),**19.
21. Moore, N. (1997) A review of reimbursement policies for alternative and complementary therapies. *Alt. Ther. Health Med.* **3(1),** 26. Also see Lopez, L. (1996) Managed care cautiously embraces complementary medicine. *J. Man. Care Pharm.* **2(6),** 631. I also interviewed officials from many of these plans from November 1996 through January 1997.
22. A Washington state law, effective January 1996, requires health insurance plans in the state to provide access to every category of healthcare provider to treat conditions that would be covered under the state's basic health plan. For example, if a benefit plan covered back pain, a subscriber would not be limited to conventional medicine in seeking treatment. See discussion of law in the sixth section, infra.
23. My own situation is a good case study. I asked my allergist recently to update my food allergy profile. He performed the tests, reported on the substances that I was more or less allergic to (on a scale of 1–5) and left it at that, leaving me thoroughly confused. For example, reading though a holistic book on treating sinusitis, I learned that I should avoid milk products, which tend to be highly mucous-producing. Soy products are suggested as an alternative. Yet my test results indicated that I am slightly allergic to soy but not to milk. If I were an Oxford subscriber, the lack of coverage for nutritional counseling might be a deterrent to my receiving such counseling, thus probably resulting in more office visits and increased costs to Oxford.

24. Cohen, M., 157, quoting *Andrews v. Ballard,* 498 F.Supp. 1038,1053 (1980).
25. Ibid., 159.
26. Padgug, R., 154.
27. Weeks, J. (1996) Naturopathic medicine and managed care. American Association of Naturopathic Physicians, pp. 12–14.
28. UM standard 2.0 states: "Where procedures are used for preauthorization and concurrent review, qualified medical professionals supervise review decisions." (NCQA 1996 standards effective through March 1997). Qualified medical professionals are not defined. NCQA personnel were not able to determine whether this would require medical professionals to be versed in a particular CAM treatment before making a review decision.
29. Typical statutory definitions include: diagnosing, preventing, treating, and curing disease; attaching such titles as "M.D." to one's name; performing surgery; and administering or prescribing drugs. *See* Cohen, M., 90.
30. Ibid, 85.
31. *See Wilk v. AMA,* 895 F.2d 352 (7th Cir. 1990).
32. Andrews, L., 1298, 1315.
33. Legislative recognition of CAM is demonstrated by incorporating such terms as "energy flow" and "balance," in the licensing statutes. See Cohen, M., 92.
34. American Western, for example, is developing a formulary for herbal/homeopathic remedies.
35. Note that CAM treatments were not included in any of the 18 Agency for Healthcare Policy and Research (AHCPR) guidelines issued on a wide range of diseases.
36. Cohen, M., 156.
37. Gordon, J., 260.
38. Padgug, R., 156.
39. Lopez, L., 633.
40. Toran, M. (1996) Alternatives in the Mainstream. *TCM.* **July/August**, 57.
41. Jarvis, W. (1995) Alternative Medicine Requires Utmost Scrutiny. *Loma Linda U. Alumni Journal.* **November/December**, 19.
42. Padgug, R., 155.
43. Gordon, J., 270–276.

44. For example, the substances used in chelation therapy are not patentable; therefore, it has not been validated by RCTs and as a consequence is not widely accepted by conventional medicine nor covered by insurance.
45. Weber, D. (1996) The mainstreaming of alternative medicine. *Healthcare Forum J.* **November/December,** 21.
46. Results of many studies have been published, many of them in the 1995 report to OAM, *Alternative Medicine: Expanding Medical Horizons.* Yet these are still not universally accepted by the conventional medical community.
47. For example, outcomes studies, examinations of clinical practice in its natural setting, are less expensive than RCTs. Dean Ornish's Lifestyle Heart Trial, in which patient progress was monitored, was such a study. In evaluating the Ornish study, notes Gordon, we may need to be content with seeing that the approach works, without knowing whether it is really the diet, the relaxation, or the support group that really does the job.
48. Weber, D., 21.
49. McIntee, G., 61.
50. Murphy, C. (1996) Acupuncture boom. *Washington Post Health* **October 8,** 10.
51. Colgate, M. (1995) Gaining insurance coverage for alternative therapies. *J. Healthcare Market.* **15(1),** 24.
52. Notably, American Western is developing its own in-house coding plan.
53. Note also that formulary controls, commonplace among managed care plans to control prescription drug costs, has made in an initial appearance in the CAM arena. American Western is developing a formulary for herbs and homeopathic remedies.
54. Fisk, W. (1995) Multiculturism, alternative healthcare, and responsibility for belief. *Mt. Sinai. J. Med.* **62(2),** 148.
55. Gevitz, N. (1995) Alternative medicine and the orthodoxcannon. *Mt. Sinai J. Med.* **62(2),** 131.
56. Toran, M., 55.
57. Cohen, M., 87, quoting *Peckmann v. Thompson,* 745 F. Supp. 1388 (C.D.Ill. 1990, *remanded on other grounds,* 966 F.2d 295 8th Cir. 1992).
58. The practitioner must also personally examine the individual, and the administration of treatment must not violate licensing laws.

59. The Access to Medical Treatment Act filled in gaps left by the Dietary Supplement Health and Education Act (DSHEA), which established guidelines under which manufacturers could make labeling and marketing health claims for dietary supplements so long as it included a disclaimer that the contents are not intended to treat disease. DSHEA did not address, however, whether providers could recommend and dispense dietary supplements without risking FDA enforcement action. Pub. L. No. 103-417, section 1(a), 108 Stat. 4325, as discussed in Cohen, M., 146.
60. Cohen, M., 148.
61. F-D-C- Reports, "The Pink Sheet," August 5, 1996.
62. Pressley, S. (1997) Cancer doctor's practices on trial in Texas. *Washington Post,* **January 28,** p.1.
63. Cohen, M., 154.
64. Padgug, R., 154.
65. Wash.Rev.Code sec. 48.43.045 (1996).
66. WA Office of Ins. Comm. Bull. No. 95-9 (December 1995), quoted in Cohen, M., 157.
67. The carriers were told that they should have exhausted their administrative remedies before filing suit. Some carriers have filed new suits; others have settled. Note that in May 1997, the US District Court for the Western District of Washington held that ERISA (the Employee Retirement Income Security Act) preempts enforcement of the Alternative Provider Statute. *See* 967 F. supp. 424 (1997).
68. John Weeks cites a report that explored why nutritional counseling plays such a small role in conventional medicine. A finding of that report explained it within the context of insurability. To be insurable, the probability of occurrence must be considerably less than 100% or insurance would make no economic sense. The difficulty in the field of nutrition, which is usually preventive, is that it begins to approach that 100% level. *See* Weeks, J., 6, quoting Nutrition Education for Physicians: Alternative Roles for Creating and Improved System, March 1993. Ruth A. Bruer, et al. Prepared for the U.S. Department of Health and Human Services.
69. See discussion of healthcare rationing in Hall, M., et al. (1990) *Healthcare Law and Ethics in a Nutshell.* West Publishing, St. Paul, MN, 4.

Abstract

The law has long recognized the right of the mentally competent adult to determine her own means of health care. As such, the competent adult is free to shun traditional forms of medicine in favor of various alternative measures, including religious and spiritual healing. Moreover, a parent has tradionally held an almost absolute right to the custody and control of her children. The right of parental freedom includes the right of the parent to raise the child according to her religious beliefs, and she is generally free to pursue spiritual means of healing alone for her child. In fact, a majority of states provide exemptions to their child abuse and neglect laws for spiritual treatment.

The general right of a parent to make healthcare decisions on behalf of a minor child becomes problematic when the parent opts for a course of treatment for the child that not only falls outside the domain of "traditional" medicine, but seems to adversely affect the minor's health. The spiritual healing exemptions to child abuse and neglect laws are particularly troublesome in this regard.

This chapter will briefly expound upon the right of the mentally competent adult to effect her own healthcare decisions. It will proceed to consider the right of the incompetent adult to make similar choices. The chapter will then survey the treacherous terrain of treatment decisions made on behalf of children, and in particular, the difficulties engendered by spiritual healing exemptions to child abuse and neglect laws. All told, the chapter will suggest that the legal, ethical, and philosophical issues surrounding the prayer-treatment exemptions present a veritable Gordian knot, which the courts are only beginning to untangle.

Legal and Ethical Dilemmas Surrounding Prayer as a Method of Alternative Healing for Children

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Involuntarily, parents turn children into something similar to themselves—they call that "education." Deep in her heart, no mother doubts that the child she has borne is her property; no father contests his own right to subject it to *his* concepts and valuations. Indeed, formerly it seemed fair for fathers (among the ancient Germans, for example) to decide on the life or death of the newborn as they saw fit. And like the father, teachers, classes, priests, and princes still see, even today, in every new human being an unproblematic opportunity for another possession. So it follows —

— Nietzsche, Beyond Good and Evil *(1)*

> Parents may be free to become martyrs themselves. But it does not follow they are free, in identical circumstances, to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves.
>
> — *Prince v. Massachusetts (2)*

The right of the individual to control healthcare decisions has been considered an essential element of personal liberty *(3)*. Perhaps no right is held more sacred than the right of the individual to the possession and control of her own person *(4)*. Religious freedom similarly occupies a highly esteemed position among American values *(5)*. Taken together, these fundamental liberties would seem to ensure that the competent adult has a *prima facie* right to determine—within reasonable bounds—her own means of health care and accordingly is free to shun traditional forms of medicine in favor of various alternative measures, including religious and spiritual healing.

Similarly, a parent has traditionally held an almost absolute right to the custody and control of her children *(6)*. This parental right has been considered sacred *(7)*; it is cherished among our "basic civil rights" *(8)* and has been heralded a "fundamental liberty interest" *(9)*. The right of parental freedom includes the right of the parent to raise the child according to her religious beliefs *(10)*. Accordingly, the parent is also generally free to pursue spiritual means of healing alone for her child and may thus eschew more "conventional" forms of medical care. In fact, a majority of states provide exemptions to their child abuse and neglect laws for spiritual treatment *(11)*. Yet notwithstanding various rights of parental freedom, the state, under the doctrine of *parens patriae,* may intercede on behalf of the child when such intervention would serve the interest of public health, or is otherwise necessary for the health of the child *(12)*.

The general right of a parent to make healthcare decisions on behalf of a minor child becomes problematic when the parent

opts for a course of treatment for the child that not only falls outside the domain of "traditional" medicine, but seems to adversely affect the minor's health. The spiritual healing exemptions to child abuse and neglect laws are particularly troublesome in this regard and raise a plethora of legal and ethical questions which the courts have only begun to address.

This chapter will briefly expound upon the right of the mentally competent adult to effect her own healthcare decisions. It will proceed to consider the right of the incompetent adult to make similar choices. The chapter will then survey the treacherous terrain of treatment decisions made on behalf of children, and in particular, the difficulties engendered by spiritual healing exemptions to child abuse and neglect laws. All told, the chapter will suggest that the legal, ethical, and philosophical issues surrounding the prayer-treatment exemptions present a veritable Gordian knot, which the courts are only beginning to untangle.

Adult Treatment Decisions

The common law has long recognized the right of the individual to be free from non-consensual invasions of bodily integrity, and this right has been extended to include the freedom to refuse necessary life-saving medical treatment. One court has observed:

> Anglo-American law starts with the premise of thoroughgoing self-determination. It follows that each man is considered to be master of his own body, and he may, if he be of sound mind, expressly prohibit the performance of lifesaving surgery, or ther medical treatment. A doctor might well believe that an operation or form of treatment is desirable or necessary, but the law does not permit him to substitute his own judgment for that of the patient by any form of artifice or deception *(13)*.

Indeed, "[n]o right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law.... 'The right to one's person may be said to be a right of complete immunity: to be let alone' "*(14)*. Furthermore, this protection of bodily integrity includes the right of the individual to make decisions regarding his own welfare even if such choices appear unsound or even foolish to others *(15)*. Thus, reflecting on Brandeis's oft quoted dissent in *Olmstead v. United States (16)* regarding the "right to be let alone," Justice Burger suggests that this right must be held inviolate against the claims of paternalists who would deprive the individual of personal choice under the rubric of acting "in his own best interest:"

> Nothing in this utterance suggests that Justice Brandeis thought an individual possessed these rights only as to *sensible* beliefs, *valid* thoughts, *reasonable* emotions, or *well-founded* sensations. I suggest he intended to include a great many foolish, unreasonable and even absurd ideas which do not conform, such as refusing medical treatment even at great risk *(17)*.

Because of the high valuation afforded the rights of personal autonomy and bodily integrity, courts will generally hesitate to order treatment for an apparently sane adult against her will *(18)*. In fact, it is difficult to find sufficient justification for intervention in such cases in light of the well-established rule that a physician may be liable in tort for unauthorized treatment, particularly in nonemergency situations *(19)*.

Until comparatively recent times, however, the courts routinely refused the right of patients to decline necessary medical treatment on religious grounds alone *(20)*. If the religious patient appeared *in extremis* or *non compos mentis,* the courts would typically "imply" consent to life-saving treatment despite the patient's express denial *(21)*. Although the law is far from settled,

more recent decisions have begun to allow competent adults to refuse life-saving blood transfusions on religious or other grounds *(22)*. Arguably, this trend would not hold, however, where the refusal would result in the death of the patient's unborn child *(23)*, or where minor children would be abandoned in the event of the patient's death *(24)*.

The common law right to refuse medical treatment is counterbalanced by the interest of the state in protecting its citizens from unwarranted acts of self-destruction. Hence, "[w]hether based on common-law doctrines or on constitutional theory, the right to decline life-saving medical treatment is not absolute. In some cases, it may yield to countervailing societal interests in sustaining the person's life" *(25)*. The courts and commentators have commonly identified four state interests that may limit a person's right to refuse medical treatment: preserving life, preventing suicide, safeguarding the integrity of the medical profession, and protecting innocent third parties *(26)*. In practice, however, "the government's interest in compelling medical treatment has outweighed the patient's desires only when the lives of third parties were jeopardized or when the patient was not competent to refuse care" *(27)*.Thus, courts have required competent adults to undergo medical procedures against their will if necessary to protect the public health, *(28)* to prevent serious risk to prison security, *(29)* or to prevent the emotional and financial abandonment of the patient's minor children *(30)*.

Although a competent adult may ordinarily *refuse* medical treatment on religious or other grounds, this does not mean that the patient has a corresponding right to demand any particular form of conventional or alternative treatment. There are numerous direct and indirect limitations on the right of patients to seek religious treatment *(31)*. State and federal governments are free to regulate the practice of spiritual and religious healers in an effort to protect and promote public health, safety, and welfare *(32)*. The courts consistently uphold such regulations as proper exercises of the state police power and congressional interstate

commerce power, as long as the governmental authority is contained within proper constitutional limits *(33)*. The patient is furthermore severely limited in the types of demands he can make upon his attending physician—or, arguably, upon his spiritual or religious healer *(34)*. Thus,

> A patient possesses a legal right to be free *from* treatment but no equivalent legal right to *receive* treatment. A physician may be negligent if she fails to offer a treatment that is normally provided for a particular condition. If, however, a physician does not usually offer a particular drug or treatment that the patient believes would be beneficial, the patient has no legal right to demand such treatment *(35)*.

Sadly, this doctrine necessarily entails that "there is no established legal right [even] to be free from pain or to receive treatment that effectively treats pain" *(36)*.

Incompetent Adults

In theory, both competent and incompetent adults posses the right to refuse medical intervention *(37)*. Yet the incompetent clearly differs from the competent patient in light of the incompetent's inability to successfully articulate a viewpoint regarding the provision of treatment *(38)*. In such instances, the courts generally appoint a *guardian ad litem* to effectuate treatment decisions on behalf of the incompetent ward *(39)*. Because the condition of the incompetent renders it impossible to ascertain his present desires, a third party cannot state with dogmatic confidence that his treatment decision for the patient will serve to "further rather than frustrate the patient's right to control his own body" *(40)*. Nonetheless,

> the goal of decision-making for incompetent patients should be to determine and effectuate, insofar as possible, the deci-

> sion that the patient would have made if competent. Ideally, both aspects of the patient's right to bodily integrity—the right to consent to medical intervention and the right to refuse it—should be respected" *(41)*.

In situations involving an incompetent adult who had once been competent, and in which there is evidence of the individual's intent regarding treatment, the courts typically apply a "substituted judgement" standard to the decision-making process and act according to the evidence *(42)*. Where, however, there is no reliable evidence of the patient's wishes, or where the adult has never been competent, the "substituted judgement" standard is considered inappropriate *(43)*. Thus, the adult patient who has never been competent is treated no differently from a child under the mantle of *parens patriae*, and the courts generally apply a "best interests" standard to the treatment decision *(44)*. Under the "best interests" standard, the state, in its role as *parens patriae,* is expected to "behave as a responsible, loving parent would behave" *(45)*.

Decisions on Behalf of Children

Whereas adults are presumed to possess the requisite mental capacity to pursue religious or spiritual healing rather than "traditional" medical care, "[m]inors are presumed to *lack* the capacity to make their own treatment choices" *(46)*. Although mature minors have been permitted to follow their own religious preferences on occasion, parents generally bear the primary responsibility of making healthcare decisions on behalf of their minor children *(47)*. Nevertheless, the state's authority to act as a guardian for those who are unable to care for themselves is deeply entrenched in the law *(48)*. As such, the state may seek to protect children from neglect, mistreatment, and abuse through legislation providing for the removal of neglected or mistreated children from their present custodian to another, or through

statutes targeted at punishing the offender *(49)*. The courts have held that in appropriate cases the state may intercede on a minor's behalf to insure that the child is given necessary medical treatment when the custodian has unreasonably refused to supply such treatment because of religious or other grounds *(50)*.

Prayer-Treatment Exemptions

In 1975, the US Department of Health, Education, and Welfare (HEW) set forth regulations intended to implement the Child Abuse Protection and Treatment Act of 1974 *(51)*. The regulations defined child abuse or neglect in general terms as "harm or threatened harm to a child's health or welfare" *(52)*. However, the regulations specifically required that a state include a prayer-treatment exemption in its reporting scheme in order to be eligible to receive federal matching funds *(53)*. A majority of states complied with this requirement *(54)*.

In 1983, HEW's successor, the US Department of Health and Human Services (HHS) promulgated a new set of regulations that not only removed the prayer-treatment exemption requirement, but defined child neglect to include denial of medical care (55). Despite this alteration, a majority of states retained the prayer-treatment exemptions *(56)*.

The exemptions take a variety of forms. Twenty-two states have exemptions to the criminal child abuse or neglect statutes in their criminal codes *(57)*. Of these states, thirteen utilize language similar to that found in the original HEW regulations, stating that a custodian does not abuse a child "for the sole reason that" *(58)* the child is treated by spiritual means *(59)*. Nine states use somewhat stronger language, stating that spiritual treatment constitutes health care *(60)*, or that spiritual treatment is a defense to criminal prosecution *(61)*. Twenty-three additional jurisdictions have prayer-treatment exemptions,

not in their criminal child abuse and neglect statutes, but rather in various other civil and regulatory statutes, such as child-abuse reporting statutes, termination of parental rights statutes, and similar legislative enactments *(62)*. All told, forty-four states and the District of Columbia provide some form of exemption to their child abuse and neglect laws for spiritual treatment *(63)*.

Diverse language is employed to define the parameters of accepted spiritual treatment for purposes of the exemptions. Five states specifically designate an exemption for Christian Scientists *(64)*. Fifteen jurisdictions provide exemptions for parents who provide care "according to the tenets of a 'recognized' church by a 'duly accredited practitioner' "*(65)*. Two states exempt parents who treat children by "a recognized or proven method of healing" *(66)*; and three more states allow an exemption for methods "otherwise recognized by state law" *(67)*. A more expansive formulation can be found in eight states that permit an exemption to those who employ spiritual treatment "according to the tenets of any recognized religious denomination" *(68)*. The remaining sixteen jurisdictions that harbor some form of prayer-treatment exemption either grant immunity to all spiritual treatment or loosely specify spiritual treatment that is "legitimate" or practiced in "good faith" *(69)*.

The Christian Science Church is the most prevalent religion utilizing prayer healing as an alternative to "traditional" forms of medicine *(70)* and twenty-five of the forty-five jurisdictions with prayer-treatment exemptions either explicitly or implicitly limit the exemptions to Christian Scientists *(71)*. Although commentators have been critical of the prayer-treatment exemptions as "fail[ing] to protect ill or injured children in need of medical care" *(72)* adherents of the Christian Science faith do not view the spiritual treatment of children as inimical to their healthcare needs. Thus, "[d]espite the common characterization that they are making their children martyrs to their own religious beliefs, they pursue this form of healing because they believe it to be the most

effective" *(73)*. Indeed, central to Christian Science theology is the belief that the physical manifestations of disease are "produced by a radically limited and distorted view of the true spiritual nature and capacities of men and women" *(74)*. Following this tenet, "a Christian Scientist regards all forms of disease as symptomatic of an underlying condition that needs to be healed. This is the healing, or spiritual wholeness, that he or she seeks to effect through prayer" *(75)*. Under such an interpretation, prayer-treatment would arguably prove superior to, or equal with, more "traditional" forms of healing.

The Church maintains that available evidence "strongly supports the contention that healing in Christian Scientists' experience has been real, frequent, and often not explainable under ordinary medical rubrics" *(76)*. The Church has recorded 53,900 healings since 1900 *(77)*. Moreover, the Church established a database for the years 1969–1989, and during this period recorded in excess of 7,000 healings *(78)*. The reported healings included in the database consist of "virtually all classes of disease including infectious, congenital, immunological, and neurological illnesses" *(79)*, as well as the healing of "medically incurable conditions" *(80)*. This data also includes the reported healing of 2,451 children, 640 of whom had been medically diagnosed *(81)*. In some instances, letters from physicians are offered in support of testimonials *(82)*.

Christian Scientists distinguish their religion from the various "faith healing" denominations and apply the term "spiritual healing" to their own methods over the term "faith healing." This distinction reflects the Christian Science belief that healing is an effect of spiritual law and not merely a matter of personal faith *(83)*. Moreover, unlike "faith healing" denominations *(84)*, the Christian Science Church allows its members to elect either "conventional" medical care or spiritual healing practices, and its members are not pressured into accepting the latter *(85)*. Nevertheless, if "conventional" medicine is utilized, Christian Science practitioners will not

provide spiritual healing services, believing that "conventional" medicine and spiritual healing cannot be used in conjunction because "the two methods are based on different principles and pull in different directions" *(86)*.

Despite the Church's record of reported healings, at least one commentator has suggested that "there is cause to question the efficacy of its healing practices" *(87)*. Christian Scientists will not take part in medical research because of the conviction that "such activity would interfere with . . . spiritual communion with God and therefore prevent spiritual healing from being successful" *(88)*. Thus, although few empirical studies exist, *(89)* critics point to a substantial amount of indirect evidence that reflects upon the efficacy of spiritual healing practices. Records from the King County, WA, coroner's office, for example, evince that for the period between 1935 and 1955, the "death rates for Christian Scientists from diabetes and malignancy were twice the national average" *(90)*. A study comparing the longevity of graduates from a Christian Science college with the graduates of a Seventh-Day Adventist university suggests "substantially higher mortality rates" *(91)* for the graduates of the Christian Science college *(92)*. In 1972, an outbreak of polio at a Christian Science boarding school left eleven children paralyzed before state health officials were informed by an outsider *(93)*. Similarly, in 1985 an outbreak of measles occurred in a Christian Science college in which most of the 700 students had not been vaccinated. The outbreak left 120 students ill and three dead: "This is more than twenty times higher than the death rate from measles in the general population" *(94)*. The organization CHILD (Children's Health Care Is a Legal Duty), reports that during a nine-year period, five children died in one Missouri Christian Science school of illnesses that otherwise would have been highly manageable by more "conventional" forms of medicine and that "[t]hese mortality rates are substantially higher than for children of similar socioeconomic backgrounds whose parents approve of conventional medical care" *(95)*.

Legal and Ethical Dilemmas

The legal, philosophical, and ethical dilemmas engendered by the prayer-treatment exemptions are legion. To begin, the First Amendment provides, in pertinent part, that "Congress shall make no law respecting an establishment of religion, or preventing the free exercise thereof...." *(96)*. Thus, it would appear that any statute which specifically grants immunity to one religious group for actions deemed intolerable for other groups would present a *prima facie* violation of the Establishment Clause *(97)*. At one level of analysis, the prayer-treatment exemptions effectively provide that *some* religious groups must provide "traditional" medical care for their children, whereas other specified groups do not. Hence, at least one state court found the prayer-treatment exemption under its consideration to run afoul of Establishment Clause considerations *(98)*. Another court expressed reservations concerning whether the exemption at issue could withstand Establishment Clause scrutiny in light of the fact that "the [statutory] language providing an exemption only to those individuals practicing 'in accordance' with the 'practices of a *recognized* church or religious denomination by a *duly accredited practitioner thereof*' is intended for the principle benefit of Christian Scientists" *(99)*.

It might be argued, however, that merely permitting a prayer-treatment exemption *per se* need not violate the Establishment Clause. It has been observed that the government simply cannot entirely avoid aiding religion in some manner unless, of course, it actively opposes religion—and this is prohibited by the Free Exercise Clause *(100)*. Moreover, the Supreme Court has exhibited an increasing willingness to allow the state to accommodate the exercise of religion under the assumption that the accommodation permitted by the Establishment Clause is broader than that compelled by the Free Exercise Clause *(101)*. Thus, for example, in *Employment Division, Department of Human Services v. Smith,* Justice Scalia suggested that the Court's reduction of a person's

right to claim immunity from a law of general applicability under the Free Exercise Clause might be counterbalanced by a higher tolerance for statutory exemptions to general laws: "Just as a society that believes in the negative protection accorded to the press by the First Amendment is likely to enact laws that affirmatively foster the dissemination of the printed word, so also a society that believes in the negative protection accorded to religious belief can be expected to be solicitous of that value in its legislation as well" *(102)*. Nonetheless, Scalia was also quick to intimate that it is only "nondiscriminatory religious-practice exemption[s]" *(103)* that are tolerated. But, as previously noted *(104)*, the majority of prayer-treatment exemptions limit the immunity to Christian Scientists—and this is precisely the type of denominational preference that the Establishment Clause forbids.

At first blush, it might also appear that the Free Exercise Clause of the First Amendment is implicated in the prayer-treatment controversy *(105)*. After all, one might argue that a refusal to allow parents to treat their children through spiritual healing practices alone would violate the believers' free exercise of religion. In practice, however, the Supreme Court has invalidated very few laws on the basis of the Free Exercise Clause *(106)*. The Court has long held that although beliefs are protected absolutely, actions are subject to state restriction *(107)*. Moreover, as roundly declared in *Smith*: "the right of free exercise does not relieve an individual of the obligation to comply with a 'valid and neutral law of general applicability on the ground that the law proscribes (or prescribes) conduct that his religion prescribes (or proscribes)'" *(108)*.

More taxing questions concern issues surrounding the Due Process provisions of the Fifth and Fourteenth Amendments, as well as the Equal Protection Clause of the Fourteenth Amendment. Although First Amendment and Due Process concerns have dominated the legal landscape of prayer-treatment exemptions thus far, questions of equal protection merit serious discussion *(109)*.

The Fourteenth Amendment provides, in part, that no state shall "deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws" *(110)*. It is arguable, at least, that the prayer-treatment exemptions run afoul of the equal protection provision by providing a shield from prosecution for one class of persons while denying it to others. As we have seen, the exemptions take a variety of forms and employ a diversity of language *(111)*. Some states specifically designate that the exemption will apply to Christian Scientists; other jurisdictions allow exemptions for parents who provide care in accordance with the tenets of a "recognized" church by a "duly accredited practitioner;" still other jurisdictions grant exemptions to parents who employ spiritual treatment according to the teachings of "any recognized religious denomination." But this is to deny protection to those individuals who believe, in good faith, in spiritual healing, but either do not belong to any "recognized" religion, or belong to a "recognized" religion that does not advocate religious or spiritual healing as a dominant part of its theology *(112)*. In other instances, such "select" exemptions might mean that parents who claim reliance on spiritual healing can refuse "conventional" medical care, whereas parents who object to medical treatment on other grounds—such as disagreement with the child's prognosis or diagnosis—are denied the right to forgo "traditional" medical care *(113)*.

The general idea of selecting certain religious denominations for statutory exemption while denying it to others is particularly troublesome. If prayer-treatment exemptions are not permitted in at least some instances, then the state is effectively denying the right of loving parents to provide a means of health care for their children that is not only consummate with their religious faith but is one that they earnestly believe to be the most effective. If the state grants prayer-treatment exemptions to all parents, then the immunity would eviscerate an important part of the child abuse and neglect acts, because any person could theo-

retically claim that a failure to provide adequate health care for children was done in accordance with the parent's peculiar religious or spiritual convictions. If some religious practices and denominations are to be shielded from prosecution while others are not, the question becomes: "Which religious beliefs count?" The Supreme Court has consistently frowned upon the unnecessary "entanglement" *(114)* of church and state. Yet the very notion of exempting only certain religious denominations from child protection laws clearly implies that the legislature is deciding that *some* religious beliefs and practices are acceptable, but that others do not pass muster. The Christian Science Church is by no means the only denomination to favor spiritual or other religious forms of treatment over "conventional" medicine. A partial list of the denominations that propose to cure illness through prayer, and which have also been implicated in the death of children through want of medical care, would also include: The Faith Assembly, Jesus through Jon and Judy, Faith Temple Doctoral Church of Christ in God, Christ Assembly, Jehovah's Witnesses, Christ Miracle Healing Center, The Source, The Church of God of the Union Assembly, The Faith Tabernacle, and The Church of the First Born *(115)*. *Should* a legislative body determine that only *some* denominations have beliefs and practices that merit special consideration? What kind of test should the legislature apply to determine whether a particular belief system has satisfied the minimal standards necessary to qualify for such protection? Moreover, why should an individual be granted special consideration for his membership in a duly recognized church, when another person with equally cherished and deeply held beliefs is denied religious exemption because he lacks affiliation with a "recognized" religion?

Perhaps the most urgent legal conundrum regarding the prayer-treatment exemptions involves Due Process considerations. In simplest terms, whenever the Court reviews a law to determine its procedural fairness, it seeks to ascertain whether a government entity has taken an individual's life, liberty, or prop-

erty without the "due process" that is required by the Fifth and Fourteenth Amendments *(116)*. Over the years, the Supreme Court has developed an intricate weave of rules that serve to guarantee both procedural *(117)* as well as substantive *(118)* fairness in the application of the law. Due Process considerations implicated by the prayer-treatment exemptions include, *inter alia,* the admonition that a statute must not be vague and must provide adequate notice of the conduct to be prohibited *(119)*, as well as the allied maxim that the state may not prosecute a defendant for conduct that the government has misled the defendant into believing to be permissible *(120)*.

The prayer-treatment exemptions are designed to provide immunity from child abuse and neglect laws for parents who treat their children through spiritual means only. But at least four separate cases *(121)* have risen to the state supreme court level involving scenarios in which parents supposedly shielded by prayer-treatment exemptions to child abuse and neglect laws were nonetheless prosecuted for the death of their children under applicable manslaughter statutes. The decisions of *State v. McKown (122)* and *Walker v. Superior Court (123)* provide an illustrative study of the overall legal perplexity and specific Due Process considerations at issue.

In *Walker,* the defendant was charged with involuntary manslaughter and felony child endangerment pursuant to allegations that the failure to provide medical care for her four-year-old daughter constituted criminal negligence and proximately caused the child's death. The defendant moved to dismiss on the grounds that her conduct was protected by law and the statutes under which she had been charged did not give fair notice that her conduct was criminal *(124)*. On the issue of Due Process, the defendant averred, in part, that "the state must give its citizenry fair notice of potentially criminal conduct" *(125)*. Since the defendant had relied upon a prayer-treatment exemption to a misdemeanor child abuse and neglect statute in providing "treatment by spiritual means through prayer alone" *(126)* for her daughter,

she could contend that there was no notice of the point at which lawful spiritual treatment becomes unlawful *(127)*. Walker framed the argument in terms of a rhetorical question: "Is it lawful for a parent to rely solely on treatment by spiritual means through prayer for the care of his/her ill child during the first few days of sickness but not for the fourth or fifth day?" *(128)*. The court, however, rejected this contention, quoting Justice Holmes' time-worn dictum that "the law is full of instances where a man's fate depends on his estimating rightly, that is, as the jury subsequently estimates it, some matter of degree.... 'An act causing death may be murder, manslaughter, or misadventure according to the degree of danger attending it' by common experience in the circumstances known to the actor" *(129)*. The "matter of degree" that individuals relying on the prayer-treatment exemption must correctly estimate "is the point at which their course of conduct becomes criminally negligent. In terms of notice, due process requires no more" *(130)*.

A similar Due Process (and fair notice) dispute in *Walker* centered on the fact that the defendant was essentially being punished under the manslaughter and child endangerment statutes for the very activity that was expressly accommodated under the prayer-treatment exemption. The defendant accordingly argued that the statutes issued "inexplicably contradictory command[s]" *(131)* which violated Due Process by precluding "an ordinary person [from] intelligently choos[ing], in advance, what course it is lawful for him to pursue" *(132)*. The court, nonetheless, countered that the purposes of the statutes were distinguishable and that citizens are required "to apprise themselves not only of statutory language but also of legislative history, subsequent judicial construction, and underlying legislative purposes" *(133)*. The manslaughter and child endangerment statutes "protect against grievous and immediate physical harm" *(134)*, whereas the child-abuse and neglect statute merely "assures the routine provision of child support at parental expense" *(135)*. Thus, "[i]n light of these distinguishable objectives, it cannot be

said that the legality of defendant's conduct under [the child abuse and neglect statute] constitutes an 'inexplicably contradictory command' with respect to the separate requirements of [the manslaughter and child endangerment statutes]. Indeed, the legislative history of [the child abuse and neglect statute] specifically demonstrates the Legislature's unwillingness to extend the statute's religious exemption to the felony provisions" *(136)*. As such, a juxtaposition of the statutes in question effectively "provided constitutionally sufficient notice to the defendant that the provision of prayer alone to her daughter would be accommodated only insofar as the child was not threatened with serious physical harm or illness" *(137)*.

The court in *Walker* ultimately concluded that Due Process considerations would not bar the defendant's prosecution for manslaughter and child endangerment. An opposite result, however, was reached in *State v. McKown (138)*. In *McKown,* Christian Science parents were charged with second degree manslaughter for failure to provide "conventional" medical care for their 11-year-old son who died as a result of "medically treatable" complications of diabetes mellitus. In pursuing spiritual treatment, the parents relied upon a child-neglect statute that provided that the term "health care" would include "spiritual means or prayer" *(139)*. The defendants accordingly argued that their subsequent prosecution would violate Due Process because "the child-neglect statute misled them in that it unequivocally stated they could in good faith, select and depend upon spiritual means or prayer without further advising them that, should their chosen treatment method fail, they might face criminal charges beyond those provided in the child neglect statute itself" *(140)*. Quite unlike the *Walker* court, the court in *McKown* agreed and quoted at length from *United States v. Colon -Oritz* for the proposition that

> [t]he person of ordinary intelligence . . . should not have to guess at the meaning of the penalty provisions, or else those

> provisions are not sufficiently clear to satisfy due process concerns. It is not enough for . . . [legislative] intent to be apparent elsewhere if it is not apparent by examining the language of the statute. No amount of explicit reference in the legislative history of the statute can cure this deficiency *(141)*.

Thus, because the "broadly worded" and unambiguous prayer-treatment exemption did not indicate any point ("some matter of degree") *(142)* beyond which reliance upon spiritual treatment would expose a parent to criminal liability, the *McKown* tribunal concluded that "[t]he language of the exception . . . [did] not satisfy the fair notice requirement inherent to the concept of due process" *(143)*.

A related Due Process issue in *McKown* concerned "the long-established rule that a government may not officially inform an individual that certain conduct is permitted and then prosecute the individual for engaging in that same conduct" *(144)*. Since the prayer-treatment exemption expressly provided that the defendants were free to utilize spiritual healing methods, the court concluded, "the state may not now attempt to prosecute them for exercising that right" *(145)*.

In fine, *McKown* and *Walker* pull in two entirely different directions. The Supreme Court of the United States has refused to hear either case on appeal *(146)*. As such, the question of whether parents who rely on prayer-treatment exemptions may subsequently be prosecuted for manslaughter for the failure to provide "conventional" medical care for their children could scarcely be more uncertain.

Additional problems regarding the prayer-treatment exemptions abound. How far may (or ought) the state interject itself into the sanctity of the family? Should a parent or the government decide the "best interests" of children? To what extent does a child have a right to decide upon his or her own preferred method of healing apart from parental coercion or government intervention? Finally, how does a democratic society decide whether

"traditional" methods of healing ought to be preferred (or perhaps compelled) over "non-conventional" forms of treatment? If spiritual healing is not based upon a scientific paradigm *(147)*, there may be no conceptually adequate and unbiased means of comparing methodologies. The individual stemming from an empirically based paradigm can tout impressive statistics supporting the overall superiority of "traditional" medical science. But the advocate of spiritual healing may counter with his own record of reported healings and the good-faith conviction that healing is primarily the effect of spiritual, not scientific, laws *(148)*. Although the "metaphysics" of the question is undeniably academic, the repercussions remain terribly mundane.

Conclusion

The controversy regarding prayer as an alternative means of treatment for children arises from the fertile milieu of ancient, though still undecided, battles: The uneasy tension between church and state, the delicate and shifting balance between the rights of the sovereign individual and the good of the state, the latent conflict between the rights of parents and the welfare of children, and the paradigmatic acrimony between science and religious faith.

The prayer-treatment exemptions raise a plethora of legal issues: First Amendment Establishment and Free Exercise Clause considerations, Fifth and Fourteenth Amendment Equal Protection and Due Process concerns, and ancillary difficulties surrounding the issues of fairness, vagueness, and adequate notice in the application of law. The ethical and philosophical issues at play include questions of parental rights, child welfare, state intervention, religious belief and practice, alternative world-views, and the limits of human knowledge.

It has been argued that *real* progress is an illusion because the solutions to old problems merely breed new difficulties. Whatever application this dictum may have on a global or uni-

versal scale, I will leave for others to ponder. But the adage does hold true with regard to the present controversy regarding prayer as a method of alternative healing in children.

Notes and References

1. Nietzsche, F. (1968) Beyond Good and Evil, in *Basic Writings of Nietzsche,* (Kaufmann, W., trans.), Modern Library, New York.
2. *Prince v. Massachusetts,* 321 U.S. 158, 170 (1944).
3. Nobel, B. (1993) Religious healing in the courts: The liberties and liabilities of patients, parents, and healers 16 *U. Puget Sound L. Rev.* **599,** 612.
4. *Union Pacific R. Co. v. Botsford,* 141 U.S. 250, 251 (1891).
5. Nobel, p. 611.
6. Sorenson, Ewald L. (1982) Medical decision making for children: an analysis of competing interests 25 *St. Louis U. L. J.* 689.
7. Nobel, p. 636, citing *In re Hudson,* 13 Wash. 2d 673, 678, 126 P.2d 765, 768 (1942).
8. Nobel, p. 636, citing *Stanley v. Illinois,* 405 U.S. 645, 651 (1972) (quoting *Skinner v. Oklahoma,* 316 U.S. 535, 541 [1942]).
9. Nobel, p. 636, citing *Santosky v. Kramer,* 455 U.S. 745, 753 (1982).
10. Gathings, Jr., J. T. (1989) When rights clash: the conflict between a parent's right to free exercise of religion versus his child's right to life. 19 *Cumb. L. Rev.* **585,** 604.
11. Treene, E. W. (1993) Prayer-treatment exemptions to child abuse and neglect statutes, manslaughter prosecutions, and due process of law" 30 *Harv. J. Legis.* **135,** 136.
12. Ewald, p. 689.
13. *Natansan v. Kline,* 186 Kan. 393, 406-407, 350 P.2d 1093, 1104 (1960).
14. *Union Pacific R. Co. v. Botsford,* 141 U.S. 250, 251 (1891) citing Cooley, Torts, 29.
15. "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages." *Schloendorff v. Society of New York Hosp.,* 211 N.Y. 125, 129,130, 105 N.E. 92, 93 (1914).

16. *Olmstead v. United States,* 277 U.S. 438, 478 (1928) (Brandeis, J. dissenting). Brandeis states in pertinent part:

> The protection guaranteed by the (Fourth and Fifth) Amendments is much broader in scope. The makers of our Constitution undertook to secure conditions favorable to the pursuit of happiness. They recognized the significance of man's spiritual nature, of his feelings and of his intellect. They knew that only a part of the pain, pleasure and satisfactions of life are to be found in material things. They sought to protect Americans in their beliefs, their thoughts, their emotions and their sensations. They conferred, as against the Government, the right to be let alone—the most comprehensive of rights and the right most valued by civilized men. (Ibid.)

This passage was similarly cited by Justice Goldberg in *Griswold v. Connecticut* as a comprehensive summary of "the principles underlying the Constitution's guarantees of privacy." (*Griswold v. Connecticut,* 381 U.S. 479, 494 (1965). The passage has been similarly quoted by the Supreme Court no fewer than nine other times. See: *Oklahoma Press Publishing Co. v. Walling,* 327 U.S. 186 (1946); On *Lee v. United States,* 343 U.S. 747 (1952); *Poe v. Ullman,* 367 U.S. 497 (1961); *Stanley v. Georgia,* 394 U.S. 557 (1969); *Eisenstadt v. Baird,* 405 U.S. 438 (1972); *Russo v. Byrne,* 409 U.S. 1013 (1972); *Meisel v. United States,* 412 U.S. 954 (1973); *Hudson v. Palmer,* 468 U.S. 517 (1984); *Bowers v. Hardwick,* 478 U.S. 186 (1986).

17. *Application of President and Directors of Georgetown College, Inc.,* 3331 F.2d 1000, 1017 (D.C. Cir.) cert. den. 337 U.S. 978 (1964).
18. Laughran, C. W. (1975) Religious beliefs and the criminal justice system: Some problems of the faith healer. 8 *Loy. L.A. L. Rev.* 396, 411.
19. Ibid.
20. *John F. Kennedy Memorial Hospital v. Heston,* 58 N.J. 576, 279 A.2d 670 (1971); Application of President and Directors of Georgetown College, Inc., 331 F.2d 1000 (D.C. Cir.) cert. den. 337 U.S. 978 (1964): *Collins v. Davis,* 44 Misc. 2d 622, 254 N.Y. S.2d 666 (Sup. Ct. 1964); *Powell v. Columbian Presbyterian*

Medical Center, 49 Misc. 2d 215, 267 N.Y.S.2d 450 (Sup. Ct. 1965). But see: *Erickson v. Dilgard,* 44 Misc. 2d 27, 252 N.Y.S.2d 705 (Sup. Ct. 1962).

21. Laughran, pp. 411-412; *Application of President and Directors of Georgetown College, Inc.,* 331 F.2d 1000 (D.C. Cir.) cert. den. 337 U.S. 978 (1964); *Raleigh Fitken-Paul Morgan Memorial Hosp. v. Anderson,* 42 N.J. 421 201 A.2d 573 (1964) cert. den. 377 U.S. 985 (1964); *Collins v. Davis,* 44 Misc. 2d 622, 254 N.Y.S. 2d 666 (Sup. Ct. 1964).
22. *St. Mary's Hospital v. Ramsey,* 465 So.2d 666 (Fla. App. 4th Dist. 1985); *Wons v. Public Health Trust of Dade County,* 500 So.2d 679 (Fla. App. 3rd Dist. 1987) aff'd 541 So.2d 96 (Fla.1989); *In re Brown,* 478 So.2d 1033 (Miss. 1985); *In re Brooks Estate,* 32 Ill.2d 361, 205 N.E.2d 435 (1965); *In re Osborne,* 294 A.2d 372 (D.C. App. 1972).
23. *Raleigh Fitken-Paul Morgan Memorial Hospital v. Anderson,* 42 N.J. 421, 201 A.2d 573 (1964) cert. den. 377 U.S. 985 (1964); *In re Application of Jamaica Hospital,* 128 Misc. 2d 1006, 491 N.Y.2d 898 (Sup. Ct. 1985).
24. *Application of Winthrop University Hospital,* 128 Misc. 2d 804, 490 N.Y. Supp. 996 (Sup. Ct. 1985).
25. *Matter of Conroy,* 98 N.J. 321, 348, 486 A.2d 1209, 1223 (1985).
26. Ibid. See also: *Satz v. Perlmutter,* 362 So.2d 160 (Fla. Ct. App. 1978) aff'd 379 So.2d 359 (Fla.1980); *In re Spring,* 380 Mass. 629, 405 N.E.2d 115 (1980); *Commissioner of Corrections v. Meyers,* 379 Mass. 255, 399 N.E. 2d 452 (1979); *Superintendent of Belchertown State School v. Saikewicz,* 373 Mass. 728, 370 N.E.2d 417 (1977); *In re Torres,* 357 N.W.2d 332 (Minn. 1984); *In re Colyer,* 99 Wash.2d 114, 660 P.2d 738 (1983).
27. Nobel, p. 617.
28. *Jacobson v. Massachusetts,* 197 U.S. 11 (1905).
29. Commissioner of Corrections v. Meyers, 379 Mass. 255, 399 N.E.2d 452 (1979). See also: *In re Caulk,* 480 A.2d 93 (N.H. 1984); *Dept. of Public Welfare v. Kallinger,* 580 A.2d 887 (Pa. Cmwlth. 1990).
30. *Application of President and Directors of Georgetown College, Inc.,* 331 F.2d 1000 (D.C. Cir.) cert. den. 337 U.S. 978 (1964); *Holmes v. Silver Cross Hosp.,* 340 F. Supp. 125 (N.D. Ill. 1972).

31. See Nobel, pp. 625–635, 668–709.
32. Nobel, p. 668.
33. Ibid.
34. "Faith healers should be treated no differently than other alternative health care providers. A civil court should hold faith healers to a standard of reasonable care in the deliverance of their services. The application of the common law reasonable person standard can be accomplished without delving into the constitutionally protected area of church doctrine and internal regulations." Dodes, I. B. (1987) 'Suffer the little children...': Toward a judicial recognition of a duty of reasonable care owed children by religious faith healers." 16 *Hofstra L. Rev.* **165,** 176,177.
35. Rouse, F. (1994) Decision making about medical innovation: The role of the advocate. 57 *Alb. L. Rev.* **607**.

    Note, however, that in *In re Conservatorship of Wanglie,* No. PX-91-283 (Minn. Dist. Ct. Hennepin Co. July 1991) (Belios, J.), the attending physicians concluded that because of their patient's extraordinarily poor prognosis, the aggressive care she was receiving was of no medical benefit and should be discontinued. The patient's family, to the contrary, insisted that all treatment be continued. The court, in deciding the proper conservatorship of the patient, concluded that it was in the patient's best interests to have decisions about her medical care made by her husband. At least one commentator has observed:

> Judge Belois's holding gave Helga Wanglie the right to demand, and perhaps implicitly the right to receive, intensive medical treatment that at least some physicians felt was medically inappropriate....
>
> * * *
>
> The *Wanglie* decision seems to suggest that patients have the right to regulate the conduct of their physicians, even when a doctor's medical, moral, or ethical judgment would dictate a different course. The doctors caring for Helga Wanglie were forced to continue care that, in their professional judgment was inappropriate because it provided no

> medical benefit to the patient. Yet the court seemed comfortable compelling the physicians to compromise their own professional integrity for the sake of patient autonomy.

Daar, J. F. (1993) "A clash at the bedside: patient autonomy v. a physicians professional conscience" 44 *Hastings L. J.* **1241,** 1244,1245.

36. Rouse, p. 608.
37. Knepper, K. (1994-95) Withholding medical treatment from infants: when is it child neglect? 33 *J. Fam. L.* **1,** 34.
38. Ibid.
39. *Superintendent of Belchertown State School v. Saikewicz,* 373 Mass. 728, 370 N.E.2d 417 (1977); *Matter of Conroy,* 98 N.J. 321, 486 A.2d 1209 (1985).
40. *Matter of Conroy,* 98 N.J. 321, 486 A.2d 1209, 1229 (1985).
41. Ibid.
42. Knepper, p. 34.
43. Ibid., pp. 34,35.
44. Ibid., p. 35, citing *In re C.A.,* 603 N.E.2d 1171 (Ill. App. Ct. 1992), cert. den. 610 N.E.2d 1264 (Ill. 1993); *Custody of a Minor,* 379 N.E.2d 1053 (Mass. 1978); *Saratoga County Dept. of Social Servs. v. Hofbauer,* 393 N.E.2d 1009 (N.Y. App. Div. 1979); *In re Cicero,* 421 N.Y.S.2d 965 (Sup. Ct. 1979); *In re Sampson,* 317 N.Y.S.2d 641 (1970), aff'd 323 N.Y.S.2d 253 (Fam. Ct. 1971), aff'd 278 N.E.2d 918 (N.Y. 1972).
45. Knepper, p. 35, citing Griffith, D. B. (1991) "The best interests standard: A comparison of the state's parens patriae authority and judicial oversight in best interests determinations for children and incompetent patients." 7 *Issues in L. and Med.* **283,** 332.
46. Nobel, p. 635.
47. Ibid.
48. Ibid., p. 621.
49. 42 Am. Jur. 2d *Infants* 16.
50. Ibid.
51. Kondos, E. M. (1992) "The law and Christian Science healing for children: A pathfinder 12 *Legal Ref. Serv. Q.* **5,** 15.
52. Ibid.
53. Clark, C. A. (1990) Religious accommodation and criminal liability 17 *Fla. St. U. L. Rev.* **559,** 565.
54. Kondos, p. 16.

55. Gathings, p. 592.
56. Kondos, p. 16.
57. Treene, p. 140.
58. Ibid., p. 142. Treene notes that

> The "for the sole reason" language is somewhat ambiguous. It must permit more than just the invocation of spiritual treatment, and shelter some acts and omissions by the parent, or it would be meaningless. Yet it is unclear under these thirteen states' statutes just how much spiritual treatment may displace medical care. Spiritual treatment, to Christian Scientists at least, means spiritual treatment to the exclusion of all medical treatment. A broad, but plausible, reading of the "solely" language is that the exemption does not immunize the parents practicing spiritual treatment from child neglect or abuse generally, such as if the parent did not provide adequate food or shelter, but immunizes them from neglect for failure to supply medical care. A narrower reading is also possible, however. The "solely" language might permit some degree of spiritual treatment, while reserving the power to question whether certain withholdings of medical care to a child being treated through spiritual means are too extreme to be protected and thus may be judged independently of the exemption. (Ibid., pp. 142,143).

59. Treene, p. 142. The states are Alabama, Arkansas, Colorado, Idaho, Kansas, Maine, Massachusetts, Nevada, Oklahoma, South Dakota, Tennessee, Virginia, and Wisconsin.
60. Treene, p. 142. The states are Alaska, California, Minnesota, and Ohio.
61. Treene, p. 142. The states are Delaware, Indiana, New Hampshire, New York, and Utah.
62. Treene, pp. 140, 143. The jurisdictions are Arizona, Connecticut, District of Columbia, Florida, Georgia, Hawaii, Illinois, Iowa, Louisiana, Maryland, Michigan, Mississippi, Missouri, New Jersey, New Mexico, North Dakota, Oregon, Pennsylvania, Rhode Island, Vermont, Washington, West Virginia, and Wyoming.

    Treene aptly notes that the relevant statutory schemes involved in these jurisdictions suffer from the same type of ambiguous

construction discussed above. (See *supra,* note 58 and accompanying text. *See* also, Treene, p. 143).

63. Treene, p. 140.
64. Ibid., p. 143. The states are Arizona, Connecticut, Virginia, Washington, and Wisconsin.
65. Treene, p. 143. The jurisdictions are Alabama, Alaska, Arkansas, California, Colorado, District of Columbia, Georgia, Hawaii, Massachusetts, Mississippi, New Jersey, New Mexico, Pennsylvania, Virginia, and Wyoming.
66. Treene, p. 144. The states are Colorado and Louisiana.
67. Treene, p. 144. The states are Maryland, Nevada, and Tennessee.
68. Treene, p. 144. The states are Delaware, Kansas, New Hampshire, New York, Ohio, Oklahoma, Virginia, and West Virginia.
69. Treene, p. 144. The states are Florida, Idaho, Illinois, Indiana, Iowa, Maine, Michigan, Minnesota, Missouri, North Dakota, Oklahoma, Oregon, Rhode Island, South Dakota, Utah, and Vermont.
70. Treene, p. 144.
71. Ibid., pp. 143,144.
72. Le Clair, D. K. (1987) Faith-healing and religious-treatment exemptions to child-endangerment laws: Should parental religious practices excuse the failure to provide necessary medical care to children? 13 *U. Dayton L. Rev.* **79,** 97.
73. Merrick, J. C. (1994) Christian Science healing of minor children: Spiritual exemption statutes, First amendment rights, and Fair Notice. 10 *Issues L. Med.* **321,** 325.
74. Talbot, N. A. (1983) The position of the Christian Science church. 309 *New Eng. J. Med.* **1641,** 1642.
75. Ibid.
76. Merrick, pp. 326,327, quoting First Church of Christ, Scientist, Committee on Publication, "appendix: an empirical analysis of medical evidence in Christian Science testimonies of healing, 1969–1988" [hereinafter cited as "Appendix"] in *Freedom and Responsibility: Christian Science Healing for Children,* 110, 116 (1989).
77. Merrick, p. 326, citing First Church of Christ, Scientist, Board of Directors, "statement for Atlanta Centers for Disease Control," [hereinafter cited as "Statement"] in *Freedom and Responsibility: Christian Science Healing for Children,* 3 (1989).

78. Merrick, p. 326, citing "Appendix," p. 121. (Refer *supra,* note 76).
79. Merrick, p. 326.
80. Ibid., citing "Appendix," p. 120. (Refer *supra,* note 76).
81. Merrick, p. 326, citing "Appendix," p. 121. (Refer *supra,* note 76).
82. Ibid.
83. Kondos, p. 11.
84. Ibid.
85. Merrick, p. 327.
86. Ibid., citing "Statement," p. 4. (Refer *supra,* note 77).
87. Merrick, p. 328.
88. Ibid.
89. Talbot, p. 1642.
90. Merrick, p. 328, citing Wilson, G. E. (1956) Christian Science and longevity. *J. Forensic Sci.* **43,** 54,55.
91. Merrick, p. 328.
92. Ibid., citing Simpson, W. F. (1989) Comparative longevity in a college cohort of Christian Scientists. *JAMA* **262,** 1657, 1658.
93. Merrick, p. 329, citing (1990) Religious exemptions to child neglect laws still being passed despite convictions of parents 264 *JAMA* **1226**.
94. Merrick, p. 329, citing Dolnick, E. (1990) By faith. *In Health* **59,** 64.
95. Merrick, p. 329, citing Swan, R. and Swan, D. (1993) Long history of apathy in St. Louis area, in *Childrens Health Care Is a Legal Duty* (Sioux City, Iowa) pp. 4, 5.
96. U.S. Const. amend. 1.
97. "The clearest command of the Establishment Clause is that one religious denomination cannot be officially preferred over another." *Larson v. Valente,* 456 U.S. 228, 244 (1982).
98. *State v. Miskimens,* 22 Ohio Misc. 2d 43, 490 N.E.2d 931 (1984). See also, *Walker v. Superior Court,* 763 P.2d 852 (Cal. 1988) cert. den. 491 U.S. 905 (1989).
99. *Newmark v. Williams,* 588 A.2d 1108, 1112 (Del. 1991). See also, *Walker v. Superior Court,* 763 P. 2d 852 (Cal. 1988) cert. den. 491 U.S. 905 (1989).
100. Nowak, J. E. and Rotunda, R. D. (1991) *Constitutional Law (4th ed.)* West Publishing Co., St. Paul, MN, p. 1161.
101. Treene, p. 161.
102. *Employment Division, Department of Human Services v. Smith,* 494 U.S. 872, 890 (1990).

103. Ibid.
104. See *supra,* note 71 and accompanying text.
105. Free exercise challenges to prayer-treatment exemptions were raised in *Walker v. Superior Court,* 763 P.2d 852, 869–871 (Cal. 1988) cert. den. 491 U.S. 905 (1989), and *Hermanson v. State,* 570 So.2d 322, 333-35 (Fla. Dist. Ct. App. 1990), rev'd 604 So.2d 775 (Fla. 1992). See also, *Newmark v. Williams,* 588 A.2d 1108, 1110 (Del. 1991).
106. Nowak and Rotunda, p. 1206.
107. *Cantwell v. Connecticut,* 310 U.S. 296 (1940).
108. *Employment Division, Department of Human Services v. Smith,* 494 U.S. 872, 879 (1990), quoting from *United States v. Lee,* 455 U.S. 252, 263 n.3 (1982) (Stevens, J., concurring).
109. Merrick, p. 323.
110. U.S. Const. amend. 14.
111. See *supra* notes 57–69 and accompanying text.
112. Merrick, p. 323.
113. Ibid.
114. To withstand Establishment Clause scrutiny, for example, "a government act must have not only a secular purpose and a primary effect which neither advances nor inhibits religion, it also must avoid creating the type of entanglement between government and religion which might lead to an erosion of the principle of government neutrality in religious decision making." Nowak and Rotunda, p. 1164.
115. Dodes, I. B. (1987) 'Suffer the little children...' toward a judicial recognition of a duty of reasonable care owed children by religious faith healers. 16 *Hofstra L. Rev.* **165,** 165n.2.
116. Nowak and Rotunda, p. 338.
117. "[P]rocedural review is limited in scope" and "guarantees only that there is a fair decision- making process before the government takes some action directly impairing a person's life, liberty or property." Ibid., p. 339.
118. Substantive review signifies "the judicial determination of the compatibility of the substance of a law or governmental action with the Constitution....Every form of review other than that involving procedural due process is a form of substantive review." Ibid.
119. Treene, p. 136, citing *State v. McKown,* 475 N.W. 63, 67–69 (Minn. 1991) cert. den. 112 S.Ct. 882 (1992).

120. Ibid., citing *State v. McKown,* at 68,69.
121. *State v. McKown,* 475 N.W. 63 (Minn. 1991) cert. den. 112 S.Ct. 882 (1992); *Walker v. Superior Court,* 763 P.2d 852 (Cal. 1988) cert. den. 491 U.S. 905 (1989); *Hermanson v. State,* 604 So.2d 775 (Fla. 1992); *Commonwealth v. Twitchell,* 617 N.E.2d 609 (Mass. 1993).
122. *State v. McKown,* 475 N.W. 63 (Minn. 1991) cert. den. 112 S.Ct. 882 (1992).
123. *Walker v. Superior Court*, 763 P.2d 852 (Cal. 1988) cert. den. 491 U.S. 905 (1984).
124. Ibid., 763 P.2d at 856.
125. Ibid., 763 P.2d at 871.
126. Ibid., 763 P.2d at 856.
127. Ibid., 763 P.2d at 871.
128. Ibid., 763 P.2d at 872.
129. Ibid., citing *Nash v. United States,* 229 U.S. 373, 377 (1913).
130. *Walker v. Superior Court,* 763 P.2d at 872.
131. Ibid., 763 P.2d at 873, quoting from *Raley v. Ohio*, 360 U.S. 423 (1959).
132. *Walker v. Superior Court,* 763 P.2d at 873, quoting from *Connolly v. General Construction Co.,* 269 U.S. 385 (1926).
133. *Walker v. Superior Court,* 763 P.2d at 872.
134. Ibid., 763 P. 2d at 873.
135. Ibid.
136. Ibid.
137. Ibid.
138. *State v. McKown,* 475 N.W. 63 (Minn. 1991) cert. den. 112 S.Ct. 882 (1992).
139. Ibid., 475 N.W. at 64 n.3.
140. Ibid., 475 N.W. at 67.
141. *United States v. Colon-Oritz,* 886 F.2d 6 (1st Cir. 1989) cert. den. 490 U.S. 1051 (1989), quoted in *State v. McKown,* 475 N.W. at 68.
142. See *supra,* note 129 and accompanying text.
143. *State v. McKown,* 475 N.W. at 68.
144. Ibid.
145. Ibid.
146. See *supra* notes 122 and 123.
147 See *supra* notes 74,75, 86 and accompanying text.
148. See *supra* note 83 and accompanying text.

Abstract

A significant issue for pharmacy, at a time of much change for the profession, is the extent to which alternative medical practices are acceptable to the profession. More and more concerns are being expressed as increasing numbers of pharmacists sell homeopathic, herbal, and other alternative remedies. In fact, alternative medicine challenges long-standing ideologies within pharmacy, particularly the emphasis on being a scientific profession. At the same time, pharmacy is developing new professional strategies; these include more involvement in clinical aspects of health care. Despite this, the profession is not yet addressing, in any comprehensive way, the substantial public interest in alternative medicine (including self-care) and its potential impact on health care services, such as the integration of alternative medicine into conventional care.

The purposes of this review are

1. *To indicate briefly the fundamental changes occurring in the profession of pharmacy (particular attention is given to North America and the United Kingdom, where the commercial atmosphere of retail pharmacies is obvious);*
2. *To make clear that alternative medicine challenges pharmacy to examine closely ethical issues in its new trends, and that pharmacists have an obligation to study these issues as they become involved directly in selling alternative medicines or offering general advice about them; and*
3. *To promote informed discussion on such matters within and outside pharmacy.*

Alternative Medicine

Ethical Challenges for the Profession of Pharmacy

John K. Crellin, M.D., Ph.D.

> We urge pharmacists not to stock homeopathic remedies and to inform customers that such products simply don't work. We also hope that pharmacy educators, journal editors, and pharmacy organizations will regard this as an important ethical issue. *(1)*

> While it may make good business sense [for pharmacists] to sell homeopathic products, you must listen to a higher voice, one which speaks to you about the more lasting issues of honor and integrity. *(2)*

Introduction

No doubt exists that the general growth of alternative medicine in recent years, including increasing sales of homeopathic and herbal preparations in pharmacies, highlights many ethical

issues for the pharmaceutical profession. In a recent "case history" discussion—in which a patient asks a pharmacist about a homeopathic preparation ("Now tell me, Mr. Drug Expert, how does this stuff work, and is it really any good?")—Robert Veatch points out that the case raises issues over truth-telling, informed consent, reporting potentially incompetent colleagues, and the allocation of hospital resources *(3)*. Veatch goes on: "But it also raises a much deeper issue. What is at stake in this case is our basic understanding of the nature of reality and the laws of science: what philosophers call metaphysics" *(3)*.

Although homeopathy has been a particular vexing issue in recent pharmacy literature, concerns and issues also arise with the sale of herbs and aromatherapy products as well as with the developing role of counseling among pharmacists and whether this should include advice on alternative approaches to health care.

The purposes of this review are

1. To indicate briefly that the profession of pharmacy is in the throes of fundamental change; particular attention is given to North America and the United Kingdom, where the commercial atmosphere of retail pharmacies is obvious;
2. To suggest that alternative medicine challenges pharmacy to examine closely ethical issues in its new trends, and that pharmacists have an obligation to study these issues as they become involved directly in selling alternative medicines or offering general advice about them; and
3. To promote informed discussion on such matters within and outside pharmacy.

First, however, some general background is indicated. Although pharmacists are increasingly adding homeopathic and herbal preparations to their shelves, many do not have a good understanding of the extent and depth of interest in alternative medicine among their customers. In fact, this interest is not particularly easy to determine, partly because available studies deal

less adequately with the use of alternative self-care compared with visits to alternative practitioners; however, it is clear that, overall, lay interest in alternative medicine is a popular social movement promoted by many factors *(4)*. A widely quoted figure, published in 1993, that one in three persons in the United States has used at least one unconventional therapy in the previous year—and a third of these have seen providers of unconventional therapy) can also be taken as a reasonable guide for levels of interest in Canada and the United Kingdom *(5)*. It is clear that, although many users have educated themselves in alternative self-care, advice is constantly wanted amid a changing scene with new products, regimens, and conflicting advice appearing regularly. Questions (e.g., Should I use a homeopathic, a traditional herbal, or a regular over-the-counter remedy for my hayfever?) are well known to anyone engaged in counseling on alternative medicine. Analogous questions are also commonplace for employees in many health-food stores and, perhaps, for a growing number of pharmacists, though the latter's move into selling alternative products is characterized by inconsistent levels of professional service *(6)*. In fact, confusion arises in many pharmacies as a consequence of displaying medicines in such a manner that homeopathic remedies cannot be readily distinguished from conventional over-the-counter medicines.

Trends in Pharmacy: Pharmaceutical Care; Revising Ethics; Ethical Dilemmas

One way to capture the sense of current change within pharmacy is to consider codes of ethics. It is a truism to say that codes have long served to help professions define their identities and roles, as well as to point up obligatory standards of individual behavior. However, I suggest that it is difficult to escape the opinion that most pharmacists, at least until recently, have viewed

codes as being almost exclusively oriented to standardizing the everyday practice of pharmacy. This view not only comes from a study of the history of pharmacy, but also from close observation of contemporary attitudes. One question often asked—a reminder of pharmacy's constant strivings for greater professionalism—is whether pharmacy is "really a profession?" Ever since the 19th century (albeit more so in the 20th), Anglo-North American pharmacy has faced the issue of whether retail pharmacists (who constitute the main body of the profession) are primarily "tradespeople" or "professionals" *(7)*.

Deep-rooted feelings persist within the profession that the activities and images of trader and of professional are incompatible, partly because trade may occasion conflicts of interest in dealing with a person's ill-health. This tension, indeed divisiveness, within pharmacy has been accentuated in the 20th century through such factors as the increased sale of non-health related merchandise in pharmacies, a decline in traditional pharmacy activities, such as preparing extemporaneously dispensed medicines, and the growth in numbers of pharmacists in non-commercial occupations, such as hospital pharmacy and academia.

Such changes, certainly since the 1960s, have led to much agonizing within pharmacy over its roles in changing healthcare systems. Some new activities have emerged; hospital pharmacists, for instance, have found new positions as expert advisers on drugs, but it is noteworthy that, in many respects, this reinforces a long-standing basic philosophy of pharmaceutical education. From the 19th century onward in Britain and North America, pharmaceutical education has emphasized a rigorously scientific basis, partly as a way of distinguishing pharmacy from the "sister" clinically based profession of medicine.

Despite the continuing emphasis on science, various influences since the 1960s have been nudging the profession to broaden its educational base, namely to enlarge the role of pharmacists as drug "experts," to bring them into clinical care, and to recognize psychosocial aspects of therapy. "Medical" terminology has

become increasingly noticeable as part of new directions in the pharmaceutical profession with, for instance, stress on *clinical* pharmacy and, more recently, on pharmaceutical care *(8)*. Practices viewed as pharmaceutical care are also found under such other "new" terms as community pharmacy and social pharmacy, especially in the United Kingdom. Currently, the scope of pharmaceutical care and the enthusiasm for it varies in the minds of many pharmacists—whether in the United Kingdom or in North America—depending on occupation (in retail, hospital, or industry) or interest in professionalism and influencing change; nevertheless, an essential feature of pharmaceutical care is that it contributes to what is now called—by such other health professions as medicine and nursing—patient-centerd care. Some pharmacists wish the profession to be involved directly in patient care, not only because of pharmacists' all-around knowledge of medicines, but also because of the need for more effective communication on drug issues. In fact, some look for diagnosis and prescribing by pharmacists (for a limited range of conditions) to become generally implemented. Many consider that pharmaceutical care will be the professional "salvation" of retail pharmacy racked by many changes, such as the loss of its traditional role of preparing medicines. Writers on "new" ethics for pharmacists, such as R. A. Buerki and L. D. Vottero, hope that pharmaceutical care will redefine professional pharmacy, though it has to be based on professional values, such as "compassion, faithfulness, and fairness"*(9)*. There seems to be an implied hope that virtue ethics will solve the trade/professional issue.

It is noteworthy that concepts of pharmaceutical care have emerged alongside "new" pharmacy ethics *(10)*. Since the 1960s, pharmacy has been responding—albeit slowly—to contemporary bioethics. For instance, the codes of ethics of the American Pharmaceutical Association and of the Royal Pharmaceutical Society of Great Britain now make clear pharmacists' responsibility for the "welfare" of patients *(11)*. Indeed, the 1994 code of the American Pharmaceutical Society, much less practice-ori-

ented than earlier codes, emphasizes moral obligations and virtues as fundamental principles; moreover, patient welfare, for example, is couched in terms of a "covenantal relationship between the patient and pharmacist" *(12)*. Additionally, the code states that in return for the gift of trust received from society, "a pharmacist promises to help individuals achieve optimum benefit from their medications, to be committed to their welfare, and to maintain their trust" *(13)*.

Given the "correctness" of the language of new pharmacy codes as well as such new ideologies as pharmaceutical care, the question remains: How many pharmacists see it as the way to a stable profession in the future? How is all this being interpreted and implemented by pharmacists in general with their diverse concerns, especially by those engaged in retail pharmacy and who often criticize the "leaders," academics, or theorists of the profession as "ivory towered?" In fact, it is clear that a variety of views and much ambivalence exist about current trends within pharmacy. It is not surprising that exhortations for pharmacy to develop professionally are commonly as vigorous as they have ever been. In a recent Whitney award lecture, W. A. Zellmer, in drawing attention to the changing business of health care through, for example, marketing shifts in prescription drugs—such as no longer advertising exclusively to physicians, but now also to consumers—said that "pharmacy cannot become a complete profession until its practitioners have...'depth, values, relatedness, heart and personal substance'" *(14)*.

Alternative Medicine and Its Challenge

In the context of these trends and issues, especially the new emphasis on pharmaceutical care and the new pharmaceutical ethics, the growth of interest in alternative medicine in recent years challenges the profession to examine closely the implementation of the new directions. In elaborating on this I ask,

specifically, to what extent does alternative medicine illuminate and challenge the debate whether pharmacy is a trade or profession, and the practice of pharmaceutical care?

A Five Year Debate

Of particular interest to the first of these queries is the intriguingly protracted discussion underway since 1991, albeit with quiescent periods, in the correspondence columns of the British *Pharmaceutical Journal.* Opponents and supporters of homeopathy have taken issue, often vigorously, on the question whether homeopathy is acceptable or not to those who practice a profession that is based on "modern science." Those who find homeopathy unscientific and hence unacceptable (and who generally see it as "quackery") often revisit the question whether pharmacy is a trade or profession. They state or imply that the sale of homeopathic remedies from pharmacies is unethical because it is done merely to boost trade. One 1991 correspondent stated:

> As there is no evidence to support the incredible hypothesis of homeopathy, Mr. Madge...is urging pharmacists to become involved with an elaborate pretence which exploits the ignorance of the general public. I cannot take part, as it is unethical of me to counter prescribe a counter product which I believe to be ineffective *(15).*

And a 1995 correspondent referred to the "proponents of the self-evident (yet lucrative) nonsense of homeopathy" and made clear that selling such remedies is "the business of trade, not a profession, i.e., selling without expert knowledge just to make a profit. It is even more absurd that the Council [of the Royal Pharmaceutical Society] permits alternative medicines into approved premises" *(16).*

A commonplace view found in the *Pharmaceutical Journal* correspondence is that homeopathy is unscientific because its doses are too dilute to be effective, and, further, that homeo-

pathic theory—commonly suggesting that "fingerprints" of energy from the drug are left in the solvent—is unacceptable. Many commentators also believe strongly that evidence for effectiveness is anecdotal and that homeopathy should not be promoted in the absence of modern, carefully controlled clinical trials. Furthermore, a sense of professional paternalism—that the public has to be protected—is often implicit, if not explicit. The long history of quackery—a "lesson" from history—shapes much of the contemporary opinion that patients, because of their vulnerability during ill-health and their lack of knowledge, need protection.

Also noticeable in the correspondence, as well as in general articles on homeopathy in the pharmaceutical press, is the absence of discussion, indeed of any real acknowledgement, of patient-centered ethics—of patient autonomy, patient–practitioner communication, informed consent, and so on *(17)*. In fact, when patients are mentioned in the correspondence, or reference is made to the need for pharmacists to be open-minded, often the writer seems to defend minimal restrictions in the sale of medicines: "the concept of self-selection for general sales list medicines has been accepted by our Council [of the Royal Pharmaceutical Society of Great Britain]" *(18),* wrote one pharmacist, and another stated, there is "a duty to give the public what they want" *(19)*. Correspondents, too, who stressed the need for pharmacists to be advisers on all medicines commonly placed this in the context of strengthening the profession, not patient service *(20)*.

What I wish to emphasize here is that the discussion on homeopathy not only points up the long-standing schism within pharmacy as a trade or profession, but also reveals an existing paternalistic attitude to patients, as well as a sense that the long-standing ideology that science is the bedrock of pharmacy carries overriding influence.

From my comments so far, it should be clear that a uniform response from pharmacy to alternative medicine is hardly to be

expected, as in fact is the case with other regular health care professions. It should be clear, too, that, as said, the alternative medicine movement challenges pharmacy to examine its attitudes not only to alternative medicine, but also to pharmaceutical care, its scope and its implementation. Should alternative medicine be dismissed so readily by many pharmacists on the grounds of its lack of scientifically acceptable theory and its lack of clinical trials? Does this not push aside a consideration of a broad range of issues, some previously noted by Veatch, such as the public interest in alternative medicine and demands for respect for patient self-determination and autonomy?

Responses to the Alternative-Medicine Movement

What responses—ethically sensitive ones—might pharmacy bring to the challenge from alternative medicine? What help can be drawn from published sources, even though the subject of ethics and alternative medicine has received relatively little specific attention in the bioethics or in the health professions literature *(21)*? Much of the discussion that does exist is on the "responsibilities" of physicians and nurses and rests on acceptance of the principles and methodology of science. As with much of the homeopathic discussion previously considered, many writers on bioethics argue that it is professionally unethical to promote or to encourage treatments that have not been explained scientifically, have not been subject to double-blind clinical trials, or have not met rigorous safety testing. Concern, too, is expressed over the role of placebo action insofar as it is said to involve ignorance and/or deceit on the part of the practitioner; intriguingly, this seems more an application of the view that it is unethical for pharmacists to dispense a known placebo, rather than a consideration of the general phenomenon of placebo action that exists in all treatment regimens and is as much part of conventional as of alternative care.

Contrarily, other commentators, although respecting the principles and methods of science (of importance, they say, in

determining safety and studying efficacy) open the door to a consideration of individual case histories. This is supported, in part, by the current interest in casuistry or the case-history approach to ethical decision making. Certain cases may be viewed as paradigm cases particularly when, say, "anecdotal" or historical evidence is reinforced by information from a clinical trial. A careful assessment of a case may give weight to recommending or encouraging an alternative therapy for a particular patient in certain circumstances, not necessarily as *alternative* treatment, but maybe as complementary or supportive to conventional therapy, sometimes to counteract side-effects. There is, too, a growing opinion that trials of n=1 are justified in determining appropriate management of alternative therapies. In these, treatments are examined under controlled conditions on one patient only, in ways that match much of the thrust of alternative therapies, namely tailoring treatment to the conditions and needs of individuals.

Those who take a casuistic approach in their evaluation of alternative medicine are often inclined to consider openly such matters as

1. The limitations of conventional medicine (e.g., the view that only about 20% of current medical interventions have been formally evaluated *(22)*
2. The value of assessing a broad range of evidence, including historical and ethnographical, that can be used to assess effectiveness;
3. The importance of considering the diversity of patients' needs, and
4. An appreciation of considering bioethical precepts, including the principles of autonomy, beneficence, non-malfeasance, and justice, in any relationship with a patient.

Writings on the ethics of alternative medicine thus offer, not unexpectedly, a spectrum of views. Albeit directed more to practitioners, they offer a framework to anyone offering advice. In

particular, a pharmacist's understanding of ethical issues can do much to foster self-reflection, to explore personal values and the needs of patients, to reflect on moral and individual values and their role in professional practice, to examine attitudes to and acceptance of professional codes of ethics, to recognize the limits of one's own knowledge about therapeutics and alternative medicine (about safety of products, risks, etc.), to appreciate the needs in communicating with patients and the current emphasis placed on recognizing patients' autonomy and self-determination, and to understand culturally sensitive care. Moreover, other ethical issues can be more readily kept in mind. One is, the role of informed consent, not in the sense of a patient consenting to a particular procedure, but to ensure that customers are adequately informed to be able to make informed *choices*—a key aspect of the current informed consent doctrine.

If a customer asks about a homeopathic or herbal preparation for, say, muscular aches, or even a non-drug intervention (e.g., acupressure), rather than a conventional over-the-counter preparation, sufficient information should be given so that an informed choice can be made by a "reasonable person" (or whatever are the legal requirements in a particular jurisdiction) *(23)*.

All these issues are timely ones for pharmacy, if only because of increased attention being given to counseling as part of the emphasis on pharmaceutical care *(24)*; on the other hand, it has to be recognized that pharmaceutical counseling, at least as reflected in discussions in the professional literature, is oriented more to promoting patient compliance with the use of prescription medications and, perhaps, to encourage the use of a greater number of therapies, such as over-the-counter medications if a history-taking reveals untreated problems *(25)*. Alternative medicine, given its popularity today, challenges pharmacy to consider whether this is sufficient. It may also encourage pharmacy to deal with the ambivalence that exists toward counseling. Older pharmacists often claim that advising and helping with people's troubles has long been central to their practice of com-

munity pharmacy; they may also join others in being disquieted with the increasing formal emphasis on counseling. A recent discussion of Canadian pharmacists' attitudes to counseling suggest that blunted enthusiasm may reflect lack of training on how to counsel and what to counsel about *(26)*. Schools of pharmacy are changing this, although not by paying attention to the needs of customers seeking help with alternative care.

Closing Comments

The quotes that opened this review—along with some of those in the homeopathy correspondence—reflect a widely held view within pharmacy that any healthcare practice that cannot be rationalized on the basis of current scientific knowledge or theories is unacceptable. This applies particularly to homeopathy and other practices based on concepts of energy medicine. Herbs, on the other hand, when used in allopathic doses, are less problematic for many pharmacists. This is because the actions of many herbs can be rationalized on the basis of the pharmacological properties of constituents; moreover, there is an assumption that "scientific" explanations exist for many other herbs being currently promoted. In fact, our current knowledge, based on past history of herbal medicine and chemical analysis of many herbs, suggests that, in many cases, this is probably unjustified—yet another issue for pharmacy prompted by alternative medicine.

As I have made clear, alternative medicine challenges pharmacy in a number of ways, just at the time when the profession is developing strategies to become more involved in clinical (including psychosocial) aspects of health care, and many pharmacists are beginning to retail alternative medicines. Yet, pharmacy is not addressing, in any comprehensive manner, the increasing influence of alternative medicine and the various ways many see it developing, perhaps with substantial levels of integration with conventional care.

Faith in science and scientifically validated practices is entrenched in the profession and the limitations are rarely questioned from within. The thrust of the present review is not to argue against this position. The purpose is to indicate that, given current trends within pharmacy (e.g., pharmaceutical care), significant ethical issues are not being aired and debated as might be expected. There appears to be a gulf between the leaders of the profession and the rank and file. Moreover, bearing in mind the interest of Western societies in alternative medicine, some express surprise that the profession has not, in any substantial way, offered its services to evaluate alternative practices. One of the goals of this review is to stimulate discussion; clearly there are many ethical dilemmas for pharmacy to consider, ranging from such issues as the limitations of conventional health care (and whether it is a sign of strength, rather than weakness, to acknowledge this) to the profession's changing roles and service to society.

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3. Veatch, R. (1995) Informing a patient about a homeopathic preparation. *Am. J. Health-Syst. Pharm.* **52,** 2437–2441. Quotation below, p. 2439.
4. For recent summary of alternative medicine and the view that it is a social movement, Crellin, J. K., Andersen, R. R., and Connor, J. T. H. (eds.) (1977) *Alternative Health Care in Canada Nineteenth- and Twentieth-Century Perspectives.* Canadian Scholars' Press, Toronto, Canada.

5. For U.S: Eisenberg, D. M., et al. (1993) Unconventional medicine in the United States. Prevalence, costs and patterns of use. *New Engl. J. Med.* **328,** 246–252; for other figures, especially for Canada. *See* ref. *4*. Note added in proof: A CTV/Angus Reid Poll, conducted August 1997, reported 42% of Canadians using alternative medicines and practices.
6. Specific documentation for this viewpoint is not available, but visits to pharmacies during the past two years in Canada, United Kingdom, and United States reveal that advice offered with the sale of homeopathic or herbal preparations is very fragmentary. When it exists it is often questionable.
7. For a general sense, see such texts as Sonnedecker, G. (1976) *Kremers and Urdang's History of Pharmacy.* Lippincott, Philadelphia, PA. Perhaps nothing has highlighted the tension or the controversies more in recent years than the views of Dr. Philip Brown, editor of the influential *Scrip Magazine.* In arguing that he sees no need for a separate pharmacy distribution system, he stated that it is difficult to justify the pharmacist in professional terms against changes in the market place. *See Pharmaceutical Journal* (1994) **252,** 6980. Although Brown is writing for the British scene, his remarks are equally relevant to North America.
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