

Alternative Healthcare: Past, Present and Prospects

By ACSH Staff — October 1, 1998

Americans tried living with an unregulated marketplace in the last century. Even medical licensure was undone under Jacksonian democracy. But the tide began to turn early in this century: A response to abuses in the patent-medicine industry was the 1906 Pure Food and Drug Act, which required ingredient disclosure on product labels and thus eliminated secret-formula "remedies." In 1910 *Medical Education in the United States and Canada* now more popularly known as the Flexner report was published. It cited many diploma mills and paved the way for new medical-school standards. Major reforms in medical education followed, medical licensure was re-established, and eclecticism* and homeopathy practically disappeared. The 1912 Sherley Amendment illegalized false health-related advertising claims. Use of the more dangerous herbal ingredients of the day opiates fell within the limits of the 1914 Harrison Narcotics Act. In 1933, through its book *100,000,000 Guinea Pigs: Dangers in Everyday Foods, Drugs, and Cosmetics*, Consumers' Research, Inc., began exposing the potential ramifications of managing medicines as salable until they turn out harmful. After several tragedies were highly publicized, widespread indignation moved Congress to pass the 1938 Food, Drug & Cosmetic Act (FDCA). The FDCA made submission of proof of safety a prerequisite to marketing any medicine or cosmetic. It also made proving that violators intended to deceive unnecessary for successful prosecution. The 1962 Harris-Kefauver Amendment made submission of proof of efficacy an additional prerequisite.

The Evolution of Nonstandard Medicine

What has recently been termed "alternative-complementary healthcare" (ACH) has many names. Older names for ACH include "holistic health," "holistic health care," and "holistic medicine." The defining principle of holistic health that to neglect the social and behavioral sciences in the medical and nursing management of patients ("patient care") was to fall short of scientific standards began to recede when proponents of nonstandard medicine commandeered the expression. In a critique published in a 1984 issue of *The Journal of Family Practice*, Harold Y. Vanderpool, Ph.D., depicted holistic medicine not as a distinct system of medicine but as a "hodgepodge"* in which four substantially different approaches to medicine and health are discernible: biopsychosocial diagnosis and therapy, "whole-person medical care," "high-level wellness," and "unconventional and esoteric diagnosis and healing."

The biopsychosocial approach to medicine and health, which includes the "team approach" to patient care, is scientific. It developed as new disciplines such as nutrition, psychosomatic medicine, genetics, and environmental medicine emerged. Whole-person medical care, which includes pastoral or spiritual counseling, is largely scientific. It emphasizes humanistic, moral, and religious dimensions of patient care and the patient's feelings, perceptions, beliefs, hopes, and values. High-level wellness which includes Arica, bioenergetics, primal therapy, Transactional Analysis, and Transcendental Meditation (see box on p. 18) emphasizes extraordinary good

health, self-actualization (completely fulfilling one's potential), and self-responsibility for one's health. Unconventional and esoteric modes of "diagnosis" and "healing" include acupuncture, homeopathy, iridology, reflexology, and Rolfing (see box on p. 19). It is chiefly members of the latter approach to medicine and health that became known as "alternative."

Traditionally, the noun "alternative" primarily suggests two mutually exclusive possibilities or options. During the 1970s much of the debate concerning choosing between standard and nonstandard medicine centered on laetrile (so-called vitamin B17), an alleged cancer remedy that contains a naturally occurring plant compound capable of producing cyanide. Aggressive lobbying resulted in the contra-FDCA legalization of the sale of laetrile in 25 states. The case of Chad Green a child with acute lymphocytic leukemia (ALL) who was illegally removed from Massachusetts, where a court had ordered his parents to have him treated conventionally became the cause celebre for laetrile advocates. The boy underwent laetrile "therapy" in Mexico and in October 1979 died there. The following month's issue of the *National Health Federation Bulletin* pronounced him "off of chemotherapy and looking good." An autopsy made known not only the presence in his body of leukemia but also that of cyanide, in the liver and spleen. Shortly afterwards, laetrile proved ineffective against cancer. Moreover, evidence mounted that the standard treatment for ALL was highly effective. Such findings pointed up the avoidability of Chad Green's premature death and discredited opting for non-FDA-approved agents instead of standard treatment.

The coming into vogue of such expressions as "complementary health care" and "complementary medicine" ensued. "Complementary" derives from a Latin verb that means "to fill." It suggests removing, or contributing to the removal of, a defect in a word, completing. In the field of biomedicine (science-oriented medicine), the term "complementary" traditionally refers to accessory or adjunctive, and particularly psychological, modes of patient care a physician's bedside manner, for example. In the realm of nonstandard medicine, onetime "alternatives" have largely become alleged complements ("completers") promoted as companions to biomedical methods.

It may appear that objecting to a nonstandard complementary method is unreasonable unless that method is potentially directly injurious. But *indirect* harm from such methods, which is likelier than direct harm, can be deadly. "Complementary" practitioners often use a "heads, I win; tails, you lose" strategy: they ascribe improvements in health (both subjective and objective) to the methods they've prescribed and deterioration to any standard treatment the patient has undergone. For example, because many potentially effective cancer modalities have unpleasant side effects, while most "complementary" methods are easily tolerable or even pleasurable (and are promoted with conviction and enthusiasm by practitioners), a patient's compliance with standard therapy may diminish substantially. Moreover, practitioners of nonstandard complementary methods are often hypercritical of biomedicine and profoundly committed to "holistic" ideologies. Thus, tacitly or straightforwardly, a practitioner may represent as an alternative i.e., as one of two mutually exclusive options a method that proponents generally categorize as a complement, an accessory, or an adjunct. In a 1984 issue of *Annals of Internal Medicine*, Cassileth and associates reported that 40 percent of cancer patients who had been submitting both to an "unorthodox treatment" and to a standard modality had eventually discontinued submitting to the latter.

The popularity of ACH soared in the early '90s. In 1990 the John E. Fetzer Institute was established, with an endowment of \$240 million. Its ostensive purpose was to incorporate "subjective and intuitive and appreciative ways of knowing" and American healthcare. Since its founding the institute has emphasized "consciousness and spirit" i.e., spiritualism. It funded the oft-cited and much publicized Eisenberg study "The Use of Unconventional Medicine in the United States"; produced the popular PBS series *Healing and the Mind with Bill Moyers*; funded and helped to plan and develop the Consumer Reports Books title *Mind/Body Medicine: How to Use Your Mind for Better Health* (1993); and continues to assist organizations and individuals promoting the research of, and "education" in, modes of "body-mind-spiritism."

The most important single event to further ACH in the United States was the establishment, in 1992, of the Office of Unconventional Medicine in the National Institutes of Health (NIH). The media misrepresented the office's creation as the result of a new respect for ACH in the scientific community. In fact, an Appropriations Subcommittee maneuver by a senator and an influential former congressman both of whom asserted that taking "alternative" preparations had improved their health had compelled the NIH to establish this ACH foothold. When, later that year, the U.S. Congress changed the name of the Office of Unconventional Medicine to the "Office of Alternative Medicine" (OAM), it strengthened the popular redefinition of the adjective "alternative": nontraditional, unconventional, unusual, nonestablishmentarian, or offering or allowing a choice.

The expressions "alternative medicine," "alternative healthcare," "alternative healing" and the like refer to an enormous group of systems, methods, general "approaches," and practices. Of the very few characteristics the members of this group have in common, the paramount characteristic from a consumerist standpoint is that scientific evidence of significant therapeutic, diagnostic, or preventive-medicine utility is lacking or absent. In the foreword of the 1995 NIH publication *Alternative Medicine: Expanding Medical Horizons* (popularly known as the Chantilly Report) the OAM's first major report the NIH stated:

. . . [T]his document does not reflect endorsement of these therapies or recommendations for research by the NIH, the U.S. Public Health Service, or the U.S. Department of Health and Human Services

[emphasis in original]. *It reports on a series of opinions* [emphasis added] expressed by nongovernment participants in the work-shops. . . .

The foreword also stated:

The NIH cautions readers not to seek the therapies described in this document for serious health problems without consultation with a licensed physician. The NIH further cautions that many of the therapies described have not been subjected to rigorous scientific investigation to prove safety or efficacy; and many have not been approved by the U.S. Food and Drug Administration. [emphasis in original]

Yet ACH proponents often misrepresent the Chantilly Report as a highly factual resource approved by the NIH. The disclaimer portions of the foreword have not been adequately publicized. The public would have been better served if they had been printed on every page.

On October 20, 1998, Congress passed legislation that promoted the OAM to a more self-directed entity: a "Center" with an initial appropriation of \$50 million the Center for Complementary and Alternative Medicine.

"Apocalypse" Then

Broadly, "quackery" refers to the pretensions, misrepresentations, practices, and methods of a quack any person who is unqualified or incompetent in the field to which his or her pretensions, misrepresentations, practices, and methods pertain. The word "quack" traces to two Dutch words: the obsolete verb quacken, which meant "to chatter or prattle," and *salve*, a relative of the English word "salve." Old-time quacksalvers were simply persons who bragged about the medicinals they offered.

The distinction between administering deceptive or inauthentic medicinals and trying to popularize such is important. A measure of acting imaginatively is permissible, and often desirable, in clinical medicine: For example, in patient care physicians may use pharmaceuticals in an off-label fashion (i.e., use drugs against conditions besides those for which the FDA has approved them). Moreover, standard practitioners of biomedicine occasionally use placebo methods and medicinals whose effects are either not pharmacologic or not specific to any of the patient's conditions. But legitimate practitioners do not puff, propagandize, or proselytize for such doings, nor do they present them as "alternative."

In 1983 and 1984 respectively, the U.S. Senate and the House of Representatives independently concluded that medical quackery was the leading cause of harmful consumer fraud targeting the elderly in the U.S. The House report defined "quack" as "anyone who promotes medical schemes or remedies known to be false, or which are unproven, for a profit." Corrective efforts followed. In 1986 an FDA-funded national survey yielded the finding that the use of dubious health-related products was substantial. Consumer protection efforts in this area reached their apex when Congress passed the 1990 Nutrition Labeling and Education Act (NLEA).

But many counterforces shortly rallied to fight governmental consumer-protection efforts, and the

FDA drew back from its mandate to keep dubious health products out of the marketplace. Consequently, marketing homeopathic products as "remedies," and edible herbal preparations as "dietary supplements," is perfectly lawful. It is ironic that, because the grandfathering period established by the 1962 Harris-Kefauver Amendment had ended, the FDA had in 1990 banned 223 ineffective ingredients in 19 product categories, had in 1991 banned 111 ineffective "weight control" ingredients, and had in 1992 proposed banning 415 ineffective ingredients from seven categories of nonprescription drugs.

The Clinton Administration began its tenure with an enormous effort to institute a national healthcare financing program. This was an idea whose time had come, but a disinformation campaign by the health insurance industry derailed the undertaking. In TV commercials, for example, a fictitious couple at a kitchen table speculated about how the Clinton plan could backfire.

A multitude of mainstream physicians shifted to managed care a possible free-enterprise means of resolving the healthcare financing crisis partly to prevent a governmental takeover of healthcare. The ascension of managed care has increased the eroding of medical ethics by business values and has thus reduced the public's confidence in standard healthcare. Managed-care physicians work not for patients but for HMOs, which contract with employers. Employers and HMOs are naturally more interested in saving money and maximizing profits, respectively, than in improving the health of employees and their families.

Although a government-run healthcare financing program did not materialize, expectation of such prompted lobbying by ACH practitioners for inclusion. Senator Orrin Hatch endorsed alternative medicine and sought assurances that the health fraud provisions of the Kassebaum-Kennedy Health Care Act would not "eliminate or discourage alternative treatments by threatening fraud actions under the new language of the bill." But, because virtually all of its defining methods and practices lack a scientific basis, ACH is by nature misleading. In the August 1997 issue of *Alternative & Complementary Therapies*, ACH attorney Alan Dumoff said of the aforementioned act: "The two provisions of greatest concern are new civil sanctions for a 'pattern' of billing Medicare that is found to be for services held to be not 'medically necessary,' and a provision making health fraud against any third-party payor a criminal offense." How can a "service" for which scientific evidence of safety and efficacy is deficient or absent be medically necessary?

In early 1992 an attorney who laid out health food industry concerns about the NLEA referred to four new federal regulations that reinforce truth-in-labeling requirements as "Four Horsemen of the Apocalypse" for the health food, herbal, and dietary supplement industries:

** Unfounded health claims were not to be made for foods. Enforcement of this regulation would have threatened the very meaning of "health food."*

** Herbs whose only known usage was medical were to be regulated as medicines. This regulation would have inconvenienced the medicinal-herb industry enormously. Although many herbs have therapeutic utility and some are potential safe and effective over-the-counter medicines, allowing the marketing of medicinal*

herbal products without standard quality controls and adequate label instructions is unfair to pharmaceutical manufacturers and potentially disastrous for consumers.

** The FDA was to require that the nutrient potencies of dietary supplements not exceed those of conventional foods. This regulation and that outlined next together might have caused a 40-percent decrease in dietary-supplement sales.*

** The U.S. Recommended Daily Allowances (U.S. RDAs; in 1995 renamed "Reference Dietary Intakes" [RDIs]), rather than the Recommended Dietary Allowances (RDAs), were to be the mandatory index for nutrition information on labels. Because the U.S. RDA values equaled the highest RDA values for nonpregnant, nonlactating persons, using the U.S. RDAs as the label index would have made the percentage numbers less attractive.*

In 1991 the health food industry began rallying its forces for an all-out write-in campaign designed to prevent the improvements for which the NLEA had been designed. The objective of industry leaders was to intimidate election-minded legislators into standing up for the well-heeled ACH special interests rather than for public health and consumerism. The industry used the Big Lie technique to rouse consumers. Its deceptive battle cry was "Write to Congress today or kiss your vitamins good-bye!" Many consumers wrote, and to further its cause the dietary supplement lobby donated \$2.5 million to congresspersons.

The original purpose of the NLEA was to increase consumers' ability to judge nutritional products by increasing the readability and comprehensibility of product labels. This purpose was realized with respect to food products; regarding dietary supplements, however, the NLEA backfired. Every aspect of quality control weakened. Consequently, supplement manufacturers may make on product labels unproven drug claims (claims concerning the product's alleged ability to affect the structure or function of the human body); protection against unsafe supplements diminished seriously; and persons seeking health improvement through herbs have died unnecessarily. This perversion of the NLEA did not represent the will of the people but was the result of concerted lobbying by the health food, medicinal-herb, and dietary supplement industries.

Use of ACH

Proponents of ACH have greatly exaggerated its popularity. The publication of the aforementioned Eisenberg study in *The New England Journal of Medicine* set off such exaggeration. In the abstract, the researchers stated: "One in three respondents (34 percent) reported using at least one unconventional therapy in the past year, and a third of these saw providers for unconventional therapy." Thus, only 11 percent of the respondents had reported visiting practitioners of "unconventional therapy." Furthermore, in certain forms some of the approaches to health the researchers categorized as "unconventional therapies" namely, biofeedback, commercial weight-loss programs, hypnosis, "lifestyle diets," massage, relaxation techniques, and self-help groups are at least marginally biomedical. The researchers' working definition of "unconventional therapies" was: "medical interventions not taught widely at U.S. medical schools or generally available at U.S. hospitals." They stated: "Relaxation techniques, chiropractic, and massage were

the unconventional therapies used most often in 1990." Such presumed use of "unconventional therapies" constituted 88 percent of the total presumed use.

The data from the Eisenberg survey described above did not justify the NEJM statement that "the frequency of use of unconventional medicine in the United States is far higher than previously reported." Naturopathy use was a nonfactor in the Eisenberg study, but in a landmark survey published in 1972, one percent of the respondents had reported "ever having used" a naturopath in 1969. In the Eisenberg study less than one percent of the respondents reported having used acupuncture, but in a Harris poll published in 1987, 4 percent of the respondents had reported using acupuncture. The percentage of respondents who reported having used a homeopath was low in both studies: 0.5 in 1969, 0.32 in 1990. Indeed, only an increase in the use of over-the-counter herbal and homeopathic "remedies" is evident from these studies, and the main cause of this apparent increase is probably aggressive marketing kicked off by a weakening of FDA regulations.

The highest recorded national levels for the use of nonstandard health-related methods in the U.S. were found in a 1997 survey of 1,500 adults. Forty-two percent of the sample reported having used such a method in the preceding year, but only 4.4 percent reported relying primarily on ACH. The most prevalent method was herbal "therapy," which 17 percent of the respondents reported having used but 85 percent of this use had not involved seeing a practitioner. The second most prevalent method was chiropractic, which 16 percent of the respondents reported having used. The third most prevalent method was massage (14 percent), 84 percent of which had been received professionally. Vitamin "therapy," 79 percent of which had not involved seeing a practitioner, ranked fourth (13 percent). Only 3 percent of the respondents reported having used homeopathy, and only 27 percent of the homeopathy users reported having visited a homeopath; thus, only 0.81 percent of the total sample reported having visited a homeopath. Only 2 percent of the respondents reported having used acupuncture, only 10 percent said that they would probably use it eventually, and 58 percent said that they would not. Only hypnotherapy and yoga had a similar rank.

Whither ACH?

I envision three possible futures for ACH:

The democracy-diversity scenario. Heterodoxy and social heterogeneity are compatible. The U.S. Constitution entitles citizens to freedom of religion and may be construed to entitle persons to freedom of religious and quasireligious "healing." In this scenario biomedical services and ACH will coexist peacefully, both kinds of service covered by insurance carriers and available through managed care, and the health food and supermarket industries will blend.

The pendulum scenario. The situation will reform without any public admission of wrongdoing. The ACH component of the NIH will lose its newsworthiness or, because of disparagement by the media, its popularity; then budget cuts will cause

its elimination. Managed care programs will keep eliminating services that increase expenses but do not measurably benefit patients. Malpractice suits will frighten deep pockets away from ACH. And the outrage of the public will reincline Congress toward consumer protection.

The adaptation (evolution) scenario. The trend among acupuncturists, aromatherapists, Ayurvedists, chiropractors, herbologists, homeopaths, reflexologists, shiatsuists, and other providers of health-related services that are outside the American medical mainstream will be to confine their professional or quasiprofessional practices to those that the mainstream medical community has not proscribed. Because of customer satisfaction, their niche will endure despite a lack of proof of significant therapeutic efficacy for many of their practices. Fringe practitioners who are ideologues or true believers will denounce their reasonable comrades as sellouts and will continue to operate counterculturally. Some insurance carriers may continue to cover such services, but such companies will also be countercultural.

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