Americans have been flocking to alternative medicine. Although since the advent of Western medicine it has often been scorned by the medical establishment as being of dubious merit, for thousands of years what is today called “alternative” medicine was truly the only alternative.

One type of alternative medicine that has become almost mainstream is herbal products. There has been a tradition of herbal medicine use throughout history, and many widely used pharmaceuticals are botanically derived. The difference today is that instead of getting herbs from the shaman or picking them in the field and brewing them into tea, people purchase them neatly packaged from almost anywhere, from drugstores to supermarkets to the Internet.

Many have tried an herbal-based product, whether it be echinacea to fight the common cold or gingko biloba to improve memory. Saw palmetto is even reputed to alleviate prostate cancer. What's driving the growth in herbal products, says Moira Saucer, former communications director for the American Herbal Products Association, is the trend toward “self-care—consumers want to take responsibility for their own health.”
Regulation

There is some sentiment that herbal products are not sufficiently regulated. In the May 2000 issue of Consumer Reports magazine, which featured alternative medicines, Rhoda Karpatkin, president of the Consumers Union, wrote: “When you shop for a nutritional supplement, you should have—but you don’t—the right to know the following: Is the product safe? Will the herb headlined on the label actually be present in the package? Can you be sure the product will be consistent from bottle to bottle? Is the recommended dosage sensible? Can the product interact adversely with other medications? Today, the Food and Drug Administration [FDA] doesn’t have the power to provide that protection.”

However, manufacturers’ associations like the American Herbal Products Association already believe that their industry is amply regulated. “The FDA does have authority to regulate dietary supplements despite what you read,” asserts Saucer. Herbal products are covered under the Dietary Supplement Health and Education Act (DSHEA) of 1994. By categorizing herbal products as “dietary supplements,” which means that they are treated as foods, not drugs, the FDA can regulate them only if they tout medical value, ie, if they are labeled or promoted as preventing disease. Therefore, herbal products are now labeled with the statement that they do not “diagnose, treat, cure, or prevent any disease.” Consumers are, however, using these products to diagnose, treat, cure, or prevent diseases.

Herbal Use Consequences

By ignoring any medicinal values of herbal products, DSHEA had the effect, noted one FDA official who did not wish to be named, of taking them out of the FDA’s preclearance arena. That does not mean that herbal products are off the FDA’s radar screen, however. The National Center for Complementary and Alternative Medicine (NCCAM) holds regular meetings with the FDA to enlist its cooperation in reevaluating current rules and regulations governing research on and the use of alternative medicines. Additionally, the FDA fields adverse reaction reports, submitted by physicians, family members, hospitals, poison control centers, and patients, and when it sees a pattern of problems it will take appropriate action, including public warning statements or recalls if necessary.

Mother Knows Best

The phenomenal growth in herbal products, notes Moira Saucer, former communications director for the American Herbal Products Association, has been driven by consumers who want to take responsibility for their own health. Robin Tucker, a suburban Maryland housewife who has been using alternative medicine to alleviate her and her 6-year old son’s allergies, would agree.

“The great thing about herbal remedies,” says Tucker, “is you can treat the different stages of an illness to prevent it from progressing into something more serious, whereas with conventional medicine you are only treating the worst-case scenario.”

She thanks the combination of herbal tinctures (namely, nettle and turmeric), homeopathy, and acupuncture for her son’s ability to go several months at a time without allergy shots. While the results have not been perfect, admits Tucker, her son has had no respiratory or sinus infections during that time.

Ultimately, says Tucker, “The one thing I know for sure with homeopathics is either they work or they don’t. And, unlike conventional medicine, they don’t have any negative side effects,” she claimed.

Tucker admits that her reliance on alternative medicine is something she often keeps to herself because many people either do not understand it or do not condone it. However, she believes that alternative medicine is gaining more acceptance. “Even the magazines my mother reads, like Woman’s Day and Family Circle, have articles about alternative medicines. That’s pretty mainstream.”

She notes that if any of the herbal remedies she is using now were to become available by prescription only, it would be “frustrating.” Yet she is aware of safety concerns over some herbal products. “I do think it is important to do research and heed warnings. I would never give my son anything with any side effects or psychotropic effects.” And she is quick to add that she would never give her son herbal products, like “Calm Child,” which contain St John’s wort, or anything that is purported to be mood altering.

Ultimately, notes Tucker, she, like many Americans, has been frustrated with conventional medicines and the medical establishment, particularly doctors who do not have the time to listen to descriptions of symptoms. Even if the results are not perfect, being able to treat herself gives her a sense of empowerment.
For example, a few years ago an herbal wholesaler had mixed plantain (used as a laxative) with foxglove (digitalis). While taking plantain for its laxative properties, people were experiencing cardiac stimulation from the digitalis. This caused illness in several people and led to a mass recall.

Chaparral, an herb made from a desert shrub that was promoted as an antioxidant and cancer cure, was pulled off the market in most places after the FDA fielded reports that it caused liver damage.

Currently, there is concern about the safety of ma huang (ephedra, referred to as the herbal fen-phen because it elevates blood pressure). However, its appetite-suppressing, stimulant qualities make it a popular weight-reduction aid.

In addition to adverse reactions, herbal products can react with prescription drugs in ways that are just being discovered. Currently, recent data from researchers at the National Institutes of Health (NIH) Clinical Center indicate that St John’s wort could significantly compromise the effectiveness of the protease inhibitor indinavir, an antiviral drug often used in the treatment of HIV. Findings indicated that when the 2 products are taken together, St John’s wort decreases the level of indinavir in the blood, negating its therapeutic effect.

The study’s principal investigator, clinical pharmacokineticist Stephen Piscitelli, PharmD, of the Clinical Center’s pharmacy department, noted, “Many people think that herbal products like St John’s wort are safe, but there can be dangerous interactions when taken with other medications prescribed to treat medical conditions. This study demonstrates how dangerous that interaction can be and how important it is for patients to keep their physician and pharmacist informed about any use of herbal products.”

Monitoring Alternative Medicine
After numerous surveys revealed that many Americans are using alternative medicines—and spending billions of dollars a year on them although they have not been rigorously evaluated—a movement began to encourage the government to assess their efficacy.

“The herbal field overall has outstripped the pharmaceutical industry as far as total sales are concerned,” notes George Jackson, MD, a forensic toxicologist with National Medical Services (NMS), an independent clinical forensic laboratory based in Willow Grove, PA, that offers clinical, occupational, forensic toxicology, and biopharmaceutical services.

Although Jackson is not sure what percentage of NMS’s business is linked to herbal products, he says that these products are a growing part of the business. Testing of herbal products currently pertains to product integrity primarily. “Our role is to identify any potential contaminant that may be in the product [and] to provide an analytical service to our client, as well as interpretations of our findings.” The laboratory’s clients are attorneys and manufacturers, as well as some local, state, and federal agencies.

When the laboratory tests an herbal product, it checks for content and impurities, such as pesticides (including insecticides), and metals; it does not test for potency or efficacy. The laboratory equipment used to test herbal products is generally the same as that used for other products. However, NMS’s research and development department is currently investigating the development of assays for biologic monitoring of herbal preparations. Jackson says that many laboratories are investigating this area now; because herbal products are so widely used, there is a market demand from physicians and...
In 1992, the NIH formed what would eventually become the NCCAM. The Center’s congressional mandate is to “facilitate the evaluation of alternative medical treatment modalities.” Starting as an office with a $2 million budget and no grant-making authority in 1993, NCCAM was elevated to NIH’s newest center in 1998, and its budget grew to $68.7 million in fiscal year 2000. Because NIH’s budget is congressionally appropriated, it can be concluded that the public is increasingly interested in alternative medicine and wants to see it adequately researched.

NCCAM’s new director, Stephen Straus, MD, notes, that he intends to keep an open mind about alternative medicines, but adds, “I believe well-designed and well-executed clinical research must be the essential factor in NCCAM’s search for scientific truth.”

The NCCAM Web site defines complementary and alternative medicine as covering a “broad range of healing philosophies, approaches, and therapies. Generally, those treatments and health care practices are not taught widely in medical schools, not generally used in hospitals, and not usually reimbursed by medical insurance companies.” A host of complementary and alternative medicines are listed by NCCAM. These include acupuncture (the Chinese practice of inserting needles into specific bodily areas for therapeutic purposes); homeopathy (the administration of minute doses of drugs that would produce in healthy persons symptoms like those of the disease treated); and ayurvedic medicine (a 2,000-year-old medical practice from India that includes a wide range of treatments including dietary measures, massage, medicinal herbs, and meditation). Herbal products are listed under biologically-based therapies, or “phytotherapies.”

In the herbal arena, NCCAM is coordinating several clinical studies, including a 5-year gingko biloba trial for dementia and a 4-year St John’s wort study for depression. If St John’s wort were indeed found to be effective in curing depression, it would have a dramatic impact in that it would not have the side effects of prescription drugs such as fluoxetine (Prozac). The reported annual cost to the nation of this illness is as much as $44 billion in treatment, disability, and lost productivity, according to the National Institute of Mental Health.
Marketing Misconceptions

John Renner, M D, president of the National Council for Reliable Health Information, a nonprofit group that exposes medical deception, notes that while patient self-care has long been an American tradition, this trend has intensified as managed health care has grown. "[When] primary care doctors and nurse care practitioners... became less accessible... people got frustrated. And as medical costs went up, the use of things like self-diagnostic products has increased." Renner is grateful that NIH is finally conducting research on herbal products and other alternative medicines, noting that he has no problems with herbs that have been researched. "The marketing people try to make it sound like herbs are a lot safer than medicine," says Renner, "but medicine has gone through safety tests. Most herbs have not. Natural does not mean safe."

Pointing to the dangers of some herbal products (Renner claims that ma huang has "killed perfectly healthy people"), Renner also notes that there are differences in formulation among herbs. For example, he notes, a product called PC-SPES (which stands for "Prostate Cancer Hope," from spes, the Latin word for hope), made from 8 different Chinese herbs, seemed to show promise in the treatment of certain types of prostate cancer. But unscrupulous manufacturers, riding on the coattails of the publicity, produced sound-alike products with differing—and unproven—cocktails of herbs. "The unfortunate thing is that the marketing is way ahead of the research," Renner said. "And frankly, what's brought us good ethics and science in this country is when the science is way ahead of the marketing. It's easy to market things if there's..."
as the Cambridge Heart Antioxidant Study, appeared to so overwhelmingly support vitamin E's role in thwarting heart disease that the study was stopped and vitamin E was quickly touted for its ability to prevent heart disease.

Two subsequent studies yielded more neutral results: the 1999 Gissi Prevention Trial in Italy, and the 2000 Heart Outcomes Prevention Evaluation in Canada.

The FNB did recently raise the RDA for vitamin E in both men and women from 10 mg to 15 mg from food. Upper limits were set at 1,000 international units, above which there is an increased risk of hemorrhagic damage due to the vitamin's anticoagulant properties.

Establishing upper levels gives consumers tremendous leeway since those levels can be dozens of times higher than RDAs. For example, RDAs for vitamin C are 75 mg for women and 90 mg for men, but the upper level is 2,000 mg. However, the FNB, says Schlicker, “can think of no reason that we know of to consume above the RDA. But if people want to take more than the RDA, go ahead.”

The FNB has established 7 different panels to set upper limits. Upper limits have already been established in calcium and bone-related nutrients, B vitamins and choline, and antioxidants and related compounds. Hopefully, by the end of the year the FNB will have completed upper levels for micronutrients and vitamins A and K. Future panels will cover macronutrients, electrolytes, and other food components.

Ultimately, the FNB stated, in a press release issued in April, that “insufficient evidence exists to support claims that taking megadoses of dietary antioxidants, such as selenium and vitamins C or E, or carotenoids, including beta-carotene, can prevent chronic diseases. In fact, extremely large doses may lead to health problems rather than confer benefits.”

good research on them. It's also more ethical to do that, but right now there seems to be a great interest in just the economics of the situation.”

Rhoda Karpatkin of Consumers Union wrote in the May 2000 issue of Consumer Reports, “We believe the FDA should have the authority and funding to establish basic rules regarding herbal and nutritional supplements, to require appropriate labeling, to establish consistent manufacturing standards, and to require reasonable evidence of safety.”

Renner thinks it will take some “disasters” before consumers demand more regulation. At the moment, however, requests for increased funding to beef up the FDA's monitoring of herbal products have been denied. The spokesperson from the FDA says, “If citizens have a problem with [DHSEA], they need to go to whoever writes the law. This is what the American public wanted—they wanted easy access to dietary supplements and herbals, which is why the law is written the way it is.”

A ground swell of revolt does not seem immediately forthcoming from American consumers, who relish the opportunity to treat themselves, and for whom herbals often hold a promise of hope. Sen Orrin Hatch (R, Utah), the driving force behind DSHEA (allegedly because so many herbal manufacturers come from Utah), noted, “DSHEA guarantees the right of Americans to have access to the traditional supplements that consumers have used for centuries,” as quoted by the Council for Responsible Nutrition.

In his lifetime, Renner has seen numerous health care fads come and go. He is amazed at the current rush to shark cartilage and magnets. “We've had hula hoops and magnets. Too bad hula hoops didn't have some mystical health benefit.”

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