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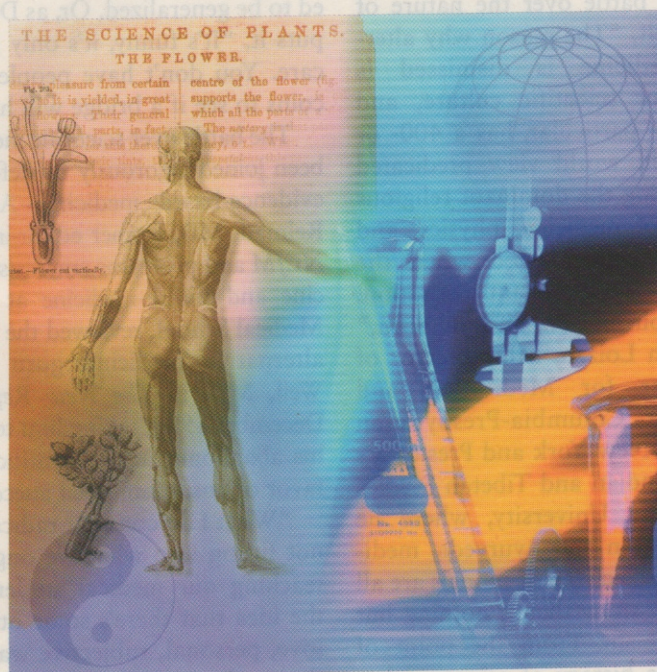
The Test of Science

How should we evaluate alternative therapies?

By Lauren M. Walker

There is no alternative medicine," the editors of the *Journal of the American Medical Association* wrote in 1998.

"There is only scientifically proven, evidence-based medicine supported by solid data or unproven medicine, for which scientific evidence is lacking."



Still, use of therapies that commonly fall under the rubric "alternative" — most of them relatively unproven — continues to grow. In a 1998 *JAMA* article, David Eisenberg, MD, reported that 42% of Americans used at least one alternative treatment in 1997, up from 34% in Dr. Eisenberg's groundbreaking 1990 study.

With that many patients using alternative methods, a public health argument can be made for examining them — at least those most widely used — scientifically. Congress seems to agree. It expanded the former Office of Alternative Medicine into a National Center for Complementary and Alternative Medicine in 1998 and raised its fiscal year 2000 budget to \$68.7 million from \$50 million the year before.

STEPHANIE DALTON COWAN

But the study of alternative medicine remains controversial. A scathing editorial in the *New England Journal of Medicine* in September 1998 characterized alternative medicine primarily by its lack of scientific testing and took advocates to task for "deny[ing] the need" for such testing. "Many advocates of alternative medicine . . . believe the scientific method is simply not applicable to their remedies," the editors wrote.

While NCCAM's three-year, \$4.3 million, randomized, placebo-controlled, double-blind study of the safety and efficacy of St. John's wort, widely used for depression, is now under way, those who study alternative medicine question the universal application of that research model. Developed for and particularly well-suited to refined, single-effect pharmaceuticals, the randomized, controlled trial seems appropriate to herbs, such as St. John's wort, that are used very much as drugs to address specific conditions. Are alternative therapies so different that they require a different interpretation of scientific method?

A New Research Design?

"In some cases, a double-blind, placebo-controlled trial works well for herbs because we can put them in the model of a drug," explains physiologist Fredi Kronenberg, PhD, director of Columbia University's Richard and Hinda Rosenthal Center for Complementary and Alternative Medicine, one of the first 10 specialty research centers funded by the NCCAM. "However, most herbs in traditional cultures are given as part of a whole system of medicine. It's 'take this herb and do this exercise and change your diet' — a multidimensional treatment. In most herbal traditions, you're diagnosed, you're given an herbal remedy, you come back. If your symptoms have changed, you may get different herbs, you may get different doses. That's much more difficult to study. How do you study a model where things are changing as you go along? Do we want to squeeze this all into the Western medical model, or is that going to change the whole way that this medicine differs from drugs, from purified-compound medicine?

"We can do this in part with outcome studies and remain as true as possible to the system being studied," Dr. Kronenberg continues. "We can also then begin to examine the sub-components. We want to be careful not to change the way these things are practiced and not force them into a research model that may not be the most appropriate."

Dr. Kronenberg and her colleagues recognize the challenge but do not back down from it. "What's been exciting at the center," she says, "is that we bring them together; we put the methodologists, study design people, and biostatisticians in the same room with the Chinese practitioner and the Ayurvedic practitioner and the tai chi practitioner and say, 'How can we study what it is that you do with a rigorous scientific design?'"

Prioritizing Limited Funds

Critics of alternative medicine argue that money spent studying some therapies is merely wasted. Stephen Barrett, MD, a retired psychiatrist, author of several books on health fraud, and founder of the Quackwatch Web site, observes that "somebody has to set research priorities. Priorities have traditionally been given to methods that have the most promise, either because they make the most sense or because they have something unusual to offer, or, at times, because people have a special interest in them. What has happened with alternative medicine is the government has intruded into the process. They set up a funding mechanism and an organization to issue grants to methods that allegedly weren't getting sufficient attention."

Dr. Barrett also favors funding decisions that consider whether a study's findings are likely to have practical effects. "If you do a research project and nobody pays any attention to the results, does it make sense to do it? For a lot of alternative modalities it's a waste of money because nobody who believes in it is going to have their mind changed by any research,

and nobody who doesn't believe in it is going to have their mind changed by any research. You've earmarked this money to study something alternative. My question is, is there something else that's more important that's going to be neglected? I don't know, but I do know there are many potentially valuable projects that are going unfunded."

The Physics of Medicine

While much of the controversy may be attributed to battles over ever-scarce research dollars, others see an underlying battle over the nature of science itself. "The reason why alternative medicine is dismissed is because our scientific culture, and medicine in particular, has a 400- or 500-year-old world view predicated on disproving the dominant religious paradigm of medicine, physics, and physiology that existed when the church was the dominant institution: vitalism, spiritualism, and animism," says Joseph Loizzo, MD, director of the Center for Meditation and Healing at Columbia-Presbyterian Eastside in New York and President's Fellow in Indian and Tibetan Studies at Columbia University, where he studies Tibetan and Ayurvedic medicines. "The mechanistic models are all designed to show there's nothing but the mechanism. From the point of view of the history of science, what they're really showing is that the church was wrong when they said there was a spirit or vital principle. But the problem is, we're not just like machines."

"So all of our science is based on this somewhat archaic war over who's right, the church or the mechanists," says Dr. Loizzo. "If you say anything that sounds remotely like 'the mind has an effect; there's something subtle that isn't like a machine influencing what's happening,' Western physicians are all trained to dismiss it as a superstition, but our mechanism has now become the counter-religion. It's a paradigm that derives from modern Newtonian physics, and that's no

longer the sole paradigm even in physics. Quantum mechanics and wave mechanics leave a lot more room for subtle things to influence concrete things."

Physicists, however, note that although quantum theory may change our understanding of submicroscopic activity, that doesn't change the fact that Newtonian laws work very well to explain macroscopic activity. If you push something hard enough, it still falls over. The notion of the observer's effect has a specific meaning in quantum mechanics that was never intended to be generalized. Or, as Dr. Barrett puts it, "It's funny, it's only in health care. You don't have people flipping coins to see if a bridge will hold up."

The battle over scientific method has been joined vigorously by defenders of evidence-based medicine. Arnold S. Relman, MD, former editor-in-chief of *NEJM* and professor emeritus of medicine and social medicine at Harvard Medical School, reviewed the works of alternative medicine guru Andrew Weil, MD, in *The New Republic* in December 1998, taking him to task for his abandonment of scientific rigor in favor of unsubstantiated anecdote.

"What I do consider radical — and not fitting into what we ought to be teaching our medical students — is the idea that there's some other intuitive, personal, subjective way of getting at the truth that does not require the marshaling of objective evidence," cautions Dr. Relman. "And that's my argument with Andrew Weil and with all alternative medicine practitioners. It's their suggestion that there's really a better way, or an acceptable alternative way, of finding out what's true."

In Search of Evidence

One alternative to the alternativists' nonmaterial interpretations of clinical results may involve the placebo effect. "Alternative practitioners make passionate claims that their patients feel better during treatment," observes Gerald Neuberg, MD, associate clinical professor of medicine and director of the intensive care unit at New York

Presbyterian's Allen Pavilion (and a member of the advisory board for Quackwatch). "Patients probably do feel better, since the placebo effect is potent medicine. We all could build pretty successful practices by dispensing little else. But since controlled clinical trials generally have not been performed, the problem is how to distinguish the psychotherapeutic benefit of treatment from the actual effects of the specific treatment.

"We as clinicians all need to learn about alternative practices because our patients ask us about what they read and hear," says Dr. Neuberg. "So it's becoming more important for practicing physicians to have some familiarity

with the alternative modalities and to try to figure out what advice to give people. The bottom line for all of us: We should want to know whether our treatments are safe and effective, regardless of whether they're natural or synthetic. If people want real answers, they need to support more clinical research, and the public should be demanding it." **H**

Lauren M. Walker is senior editor of Hippocrates.

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