complementary therapies. As a result, the majority of patients who use complementary therapies have not informed their doctors, and the subsequent lack of scientific scrutiny has opened the door for quacks.

But skepticism is not limited only to proponents of mainstream medicine. David Edelberg, chairman and medical director of the American Holistic Centers Limited of Chicago, Illinois, said that he has often heard complementary practitioners say, "I'm going to protect you from doctors." Edelberg, who is also an M.D., was to discuss the issue of how to integrate conventional and complementary medicine at the conference.

One model Edelberg proposes for bridging the gap between these two medicines is to have mainstream and complementary medicine practitioners working side by side, with M.D.s making referrals, but not necessarily becoming complementary practitioners themselves. Complementary practitioners would be like "physician extenders." Although an advocate of complementary therapies, Edelberg said that he does not feel comfortable with complementary medicine practitioners presenting themselves as "total primary-care physicians" because they do not have the breadth of clinical exposure that M.D.s have. "My education took 10 years, I simply have a larger fund of knowledge of the human body," said Edelberg, who has seen "a lot of damage from alternative medicine."

The potential for harm and abuse is particularly serious with respect to advertisements and labels of complementary therapies, an issue that was to be addressed at the conference by representatives of the US Food and Drug Administration (FDA) and the US Federal Trade Commission (FTC). Unsubstantiated claims of efficacy seem disturbingly widespread. Many of the claims in "new medicine" magazines "are just cockamamy," said Edelberg who also notes that a recent study by *Consumer Reports* magazine of ten brands of the herbal product ginseng revealed that some brands did not contain any ginseng at all. Claims of efficacy must be backed up by competent and reliable scientific evidence, which can include clinical trials, said Matthew Daynard, senior attorney for the FTC. Objective claims based solely on anecdotal evidence, he said, raise concerns. But there is little incentive for companies to invest money in clinical trials for complementary therapies which often cannot be patented. Perhaps a new standard for evaluating claims about complementary therapies and products will have to be developed.

The issue of what complementary therapies insurance companies will cover also must be resolved. Richard Friedman, a professor at the State University of New York at Stony Brook, and director of research at the Mind-Body Institute at Harvard Medical School discussed the economic impact of complementary therapies and the potential for cost savings. Studies have found that for every dollar spent on the behavioral and psychological needs of patients (as the mind-body approach does), there is a subsequent reduction of between three and thirty dollars in conventional health-care costs, said Friedman. Several insurance companies have already launched pilot programs to reimburse for mind–body therapy, but they are reluctant to go public until the data from their pilot studies are available.

The public has already looked beyond mainstream medicine to complementary medicine, and now WorldMed '96 has exposed its many and diverse therapies to scientific scrutiny and taken on the complex issues of integration, regulation and economics. "There was much more penetration into the public market than they [mainstream physicians] ever dreamed," said Edelberg. "It no longer can be dismissed."

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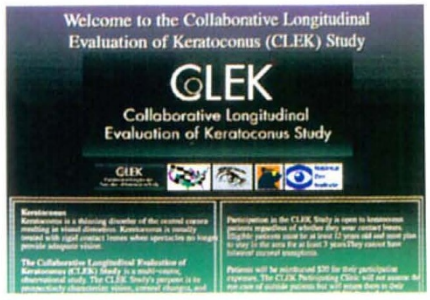
Online recruitment of clinical trial participants pays off



In June 1988, a group of optometrists and optometric researchers gathered to brainstorm for ideas for a clinical research study, something "the optometric profession has not got a great deal of experience with," says Karla Zudnick, a senior research optometrist at the University of California at Berkeley. What they hit on was a rare disorder known as keratoconus, a conical protrusion of the cornea resulting, ultimately, in the need for a corneal transplant. Nothing is known about the cause of the disease, and so the researchers reasoned that it would be a good candidate for an observational study, to attempt to discern some underlying genetic or environmental pattern, as well as gathering some information about disease progression.

Thus was born the "Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study. The goal of the study's organizers was to enroll 1,000 patients in ten months at 16 clinical centers. However, keratoconus is extremely rare (estimated at 50 persons per 100,000), making the possibility of recruiting enough patients uncertain at best (over sixty percent of the proposed clinical trials listed in the National Institutes of Health (NIH) inventory never achieve their projected sample size, and many of these are proposed studies of diseases less rare than keratoconus).

One of the tools the researchers decided to use to overcome this problem was active recruitment of patients via the Internet. "We reasoned that a reasonable proportion of people suffering the disease would have access to the Internet," says Zadnick. (Keratoconus generally strikes people between the ages of twenty and fifty years, with an average age of 29 at the onset of symptoms.) Although the majority of enrollees ultimately recruited were referred from optometric clinics, over a third of the patients that did contact the researchers via the CLEK World Wide Web Site were enrolled, a significantly high percentage for a single recruiting source.

The intense interest generated by presentations by Zadnick and her coworkers at recent meetings of the Association for Research in Vision and Ophthalmology and the Society for Clinical Trials suggests that CLEK will not be the last NIH-sponsored clinical trial to recruit people in cyberspace.

FINTAN R. STEELE