view board, Kulynych says, adding that the result may not be any faster.

But the department feels that the new rules should appease scientists who worried that health care providers wouldn't share data. "We worked very hard with the research community to take care of what they feared would be the most chilling aspects of the rule," says an HHS official. The rule goes into effect April 2003. –JOCELYN KAISER

ALTERNATIVE MEDICINE

NIH Trial to Test Chelation Therapy

The National Institutes of Health (NIH) is putting $30 million into a major clinical trial of a cardiovascular therapy that skeptics say has no scientific rationale. Even supporters of the trial acknowledge that they aren't sure how the therapy might work and that a successful trial will leave them no closer to understanding its mechanism.

Last week the National Heart, Lung, and Blood Institute (NHLBI) and the National Center for Complementary and Alternative Medicine (NCCAM) announced joint funding of a 5-year study into whether chelation therapy can help sufferers from heart disease. Chelation, whose active ingredient is a synthetic amino acid called EDTA, binds with minerals in the body and has long been an established treatment for heavy-metal poisoning. In the past 2 decades, it has also become a widely used "alternative" treatment for arterial plaque through its purported ability to draw off calcium.

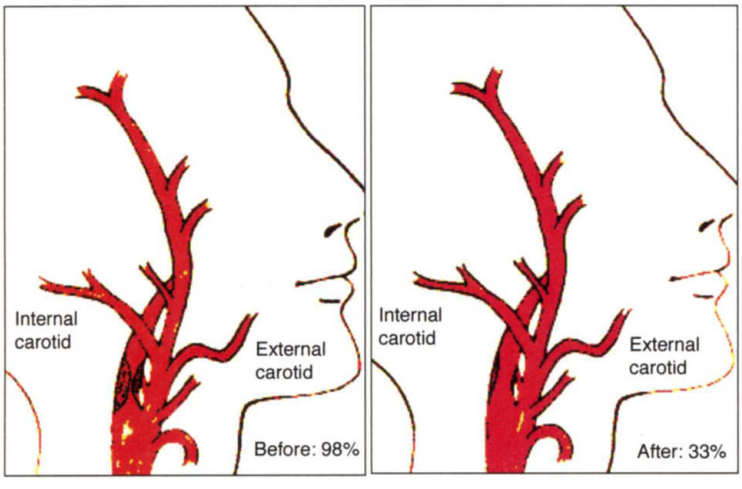
Skeptics say that the method is scientifically implausible and that the only supporting evidence is anecdotal. "The people at NIH are doing it out of political fear," says quackery battler Saul Green of New York City, a biochemist and former cancer researcher. In addition, critics believe that no amount of negative data will persuade supporters to abandon faith in the procedure. But the heart institute's Claude Lenfant says his agency is "enthusiastic" about the project. "Only a large clinical trial can definitively answer the question of whether chelation treatment is truly safe and effective," he says.

NIH has been under continuing pressure from Congress to support such research. There have been several small controlled trials that detected no benefit from the treatment, and 3 years ago Lenfant told legislators that he'd love to support a big one if he received the right proposal. The study, headed by Gervasio Lamas, director of cardiovascular research and academic affairs at Mount Sinai Medical Center and Miami Heart Institute in Miami Beach, Florida, will enroll 2300 patients at 100 sites.

Supporters of chelation offer two major theories for its action. One has it sucking the calcium from plaques and facilitating their dissolution, whereas the other involves EDTA's role as a powerful antioxidant. Lamas says that the calcium idea is "probably not a reasonable hypothesis" because, for one thing, EDTA is water soluble and therefore could not penetrate fatty membranes and affect plaque. He prefers the notion that EDTA acts primarily by decreasing oxidation of plaque-forming cholesterol.

Green and Wallace Sampson, a retired Stanford oncologist and hematologist, ridicule both theories. Calcium plays little role in plaque, they say, and chelation may actually promote rather than reduce oxidation. "When you chelate iron, you increase its ability to produce free radicals," says Green. Lamas says that it's "quite a stretch" to extrapolate from basic science and that a clinical trial offers the last word. But he doesn't promise patients a miracle: At best, he says, chelation may only stem further deterioration of blood vessels.

If the trial does show a benefit, researchers still won't know the active ingredients. The usual solution actually has 10 different components, including vitamins and minerals. But NCCAM director Stephen Straus says his primary goal is to test its efficacy. If the answer is yes, he says, "then there will be time to look at mechanisms." –CONSTANCE HOLDEN



Clear path? One case study claims that ultrasound imaging showed a two-thirds reduction in plaque in a woman's carotid artery. But experts say imaging can't tell the difference between plaque and some other type of obstruction.

CREDITS: (TOP TO BOTTOM) RICK BOWMER/AP; CHARLES J. RUDOLPH AND EDWARD W. MCDONAGH/MCDONAGH MEDICAL CENTER

ScienceScope

Pleading His Innocence A former government scientist says that he's being made "the designated fall guy" for the FBI's failure to find a suspect in last fall's anthrax mailings that killed five people.

Speaking last weekend at his lawyer's office in Alexandria, Virginia, Steven J. Hatfill, a virologist at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) from 1997 to 1999, said he "never, ever worked with anthrax in my life." Hatfill has not been named a suspect, but the FBI has searched his home twice and the media and Internet sites are full of speculation about his role in the attacks.

Hatfill is on paid leave from his current position as an associate director of the National Center for Biomedical Research and Training at Louisiana State University, Baton Rouge, after being laid off in April from his job at Science Applications International Corp. He complained that the authorities and the media have turned his life into "a wasteland."

Biodefense Buzz U.S. labs are positioning themselves to compete for the lavish sums available for bioterrorism research next year. At a meeting in Gaithersburg, Maryland, last week, National Institute of Allergy and Infectious Diseases (NIAID) officials revealed details of its plan to cover the country with some 10 "regional centers of excellence" to conduct basic and clinical research, train the next generation of biodefense scientists, and help out in case of a new attack.

The centers—the first four to be picked next May—will serve as "beehives of activity," program director Rona Hirschberg told more than 300 eager scientists and administrators. Each center will get $4 million to $6 million a year, but researchers expect that their special status will help them rake in additional funds, including hundreds of millions of dollars in regular NIAID grants. "It's a tremendous opportunity," says microbiologist Joel Baseman of the University of Texas Health Science Center in San Antonio, part of a Texas consortium that plans to apply by the 15 January deadline.

NIAID also plans to spend $450 million over the next 2 years to build and operate half a dozen new regional high-level biocontainment facilities that will be associated with the new centers.

Contributors: Constance Holden, Jeffrey Mervis, Adam Bostanci, Martin Enserink