

edited by RICHARD STONE

ILLUSTRATION BY TERRY E. SMITH

## NIH Confronts New Fraud Allegations

Still reeling from accusations that they failed to properly oversee a breast-cancer clinical trial, officials at the National Institutes of Health (NIH) are bracing for another blow.

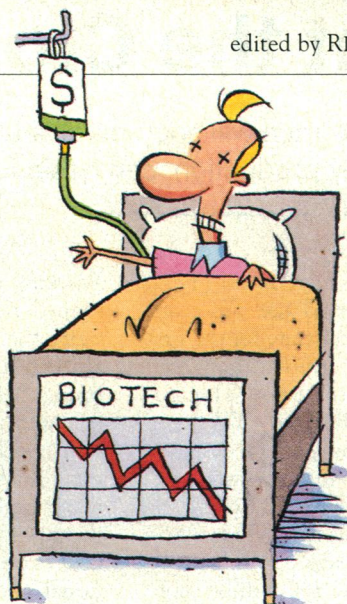
The Office of Research Integrity (ORI) is now probing "possible data falsification and fabrication" in the largest clinical trial ever sponsored by NIH's National Eye Institute (NEI). Known as the Collaborative Ocular Melanoma Study, the 8-year-old trial is assessing whether radiation treatment can prolong the lives of people with this rare cancer.

Last year, however, problems cropped up at two of the 43 study sites, says study chair Stuart L. Fine, head of the ophthalmology department at the University of Pennsylvania School of Medicine. The apparent fraud, he says, involved altering key data, such as changing the dates of photographs taken of patients' eyes.

These revelations spurred audits at the two sites. Afterwards, says Fine, "we were satisfied that data integrity would not be compromised," particularly since trial data remains unpublished and NEI has not yet made any treatment recommendations based on the trial. An employee at one site was fired, and one at the other site agreed to resign, sources told *Science*. Neither was a physician.

But the case was not closed: Last October ORI launched its own investigation of the two undisclosed sites. ORI expects to wrap up an investigation of one site in the next few weeks, though a report likely will not be released until this summer.

NEI officials say they hope to avoid the kind of delay in informing patients for which the breast-cancer trial was criticized. Originally, ORI urged NEI not to publicize problems it was investigating. But now NEI has the green light to alert study participants, which it plans to do this week, says an NEI official. In addition, investigators intend to publish a letter in a medical journal.



## Biotech to Broaden Lobbying Efforts

Fresh from a lobbying victory that eases the threat of drug price controls, the biotech industry now plans to turn up the heat on another part of the president's health care plan: Medicare reform.

Last week, representatives Lynn Schenk (D-CA) and Marjorie Margolies-Mezvinsky (D-PA), at the urging of biotech firms in their districts, persuaded Rep-

resentative John Dingell (D-MI) to oppose the president's proposed "breakthrough drug" panel that could suggest price caps on new drugs. Such a board "would be disastrous for the industry," says Prudential analyst Joseph Edelman, because it may temper Wall Street's enthusiasm for biotech stocks. Biotechnology Industry Organization (BIO) president Carl Feldbaum claims Dingell's decision is a "substantial victory" because the legislator chairs the Energy and Commerce committee, one of several with jurisdiction over health care.

But analysts say Dingell's position probably will do little to entice investors to an industry in which at least two dozen firms may have to woo new investors to avoid running out of cash in the next year. That's one reason BIO intends to fight a bill drafted by Representative Pete Stark (D-CA) that sets strict limits on payments to drug firms on behalf of Medicare patients. BIO intends to lobby legislators on Stark's Ways and Means committee.

## Green Light for U.S.-Russian Foundation?

When it comes to Western help for Russian science, good intentions don't count for much anymore. Of scores of promised aid programs, few have delivered. But now one research aid effort, unveiled more than 2 years ago, may finally pay off.

That program is a foundation to support joint American-Russian research in the former Soviet Union. The program is the brainchild of Representative George Brown (D-CA), chair of the House Science Committee, who pushed through legislation to create the foundation in 1992. The program was supposed to be endowed with up to \$25 million from a pool of money that the Defense Department was told to redirect for defense conversion aid to the former Soviet Union. But the effort floundered when the Pentagon balked at transferring money to a foundation designed for researchers of all stripes, not just weapons scientists.

But now the White House has stepped in. Last week, Jack Gibbons, the president's science adviser, told Brown the Pentagon will soon release \$10 million for the initiative, a move expected to be announced at a meeting between Vice President Al Gore and Russian Prime Minister Viktor Chernomyrdin in June.

According to the game plan, the National Science Foundation (NSF) will set up the foundation and later cut it loose as a nonprofit corporation. NSF is seeking matching funds from the International Science Foundation, which has provided much of the aid for Russian science so far.

One potential hurdle remains. Brown has recently been blasting the Pentagon for its participation in "pork barrel" projects. At press time, the Pentagon's congressional backers were retaliating by threatening some of Brown's legislation, leaving his science foundation in danger of becoming a prisoner of war. Administration officials nonetheless expect a truce in time for the June meeting.

## Mystery Lobby Backs Pittsburgh's Fisher

At first blush, it appeared to be a classic grassroots campaign. Earlier this month, the Coalition in Support of Breast Cancer Research (CSBCR) fired off letters to researchers, imploring them to voice their support for University of Pittsburgh surgeon Bernard Fisher, who has come under fire in Congress for alleged mismanagement of clinical trials sponsored by the National Cancer Institute (NCI). Strangely, however, no one seems to know who works for CSBCR. Or who funds CSBCR. Or even where it's located. CSBCR's listed address apparently doesn't exist.

Last month, Fisher resigned as director of the National Surgical Adjuvant Breast and Bowel Project (NSABP) after failing to expeditiously report potential fraud. In an unsigned 5 April letter, the CSBCR called for Fisher's reinstatement and for an investigation into NCI officials purportedly behind his removal. The campaign appears to have roused support: NCI says it's received about 100 CSBCR form letters from scientists and patients. Representative John Dingell (D-MI), who held a hearing into NSABP, has received 40 letters.

But apparently only "The Shadow" knows who runs CSBCR. A report published 22 April by *Cancer Letter*, a weekly newsletter, revealed that CSBCR's address—Suite 240, 3250 Forbes Avenue, which is located near Pitt and NSABP—doesn't exist. *Cancer Letter* concluded that "Suite 240" may refer to a mail box at a company called Mailboxes, Etc., which is located in an office building at 3250 Forbes.

The CSBCR mystery has drawn two inquiries. Renardo Hicks, director of Pennsylvania's Bureau of Consumer Protection, is fishing for CSBCR's true identity because, he says, representing a mailbox as a suite violates state law. The university is also probing the matter, although Pitt general counsel Lewis Popper insists that as far as he can tell, "no one at the University or connected to Dr. Fisher is involved." Through his lawyer, Fisher too said he knows nothing about CSBCR.