Research Group Forswears Financial Ties to Firms Whose Drugs It Tests

Members of a team of researchers planning clinical trials on anti-cholesterol drugs have composed and signed a voluntary pledge—believed to be the first of its kind—that they will not have any financial ties in the companies that produce the drugs involved in the study.

The group, led by cardiologist Bernadine Healy of the Cleveland Clinic Foundation, has published a statement to that effect in the 6 April issue of the *New England Journal of Medicine*. They said they would not hold any stock in or serve as paid consultants for the companies involved during the entire course of the study. They also pledged to furnish annual reports on any other activities, such as occasional unpaid consulting on unrelated issues for the companies.

Similar guidelines have since been adopted by the team planning Phase III of a set of trials involving drug therapy for thrombolysis in myocardial infarctions (TIMI). According to principal investigator Eugene Braunwald of Harvard Medical School, that group has gone a step further. It will forswear financial ties with the companies involved for a year following termination of the study, which will test a variety of drugs and angioplasty on angina and heart attack patients.

Concern about conflicts of interest in trials of potentially high-profit drugs has grown with the increase in university-industry collaboration in government-sponsored clinical trials. The issue was made more visible last September in a hearing held by Representative Ted Weiss (D–NY), chairman of the human resources subcommittee of the Government Operations Committee. At the hearing, witnesses testified that some researchers involved in earlier (Phase II) TIMI trials held stock or stock options in Genentech, Inc., manufacturer of the genetically engineered drug TPA (tissue plasminogen activator).

Braunwald told *Science* that he is unfamiliar with the criticisms voiced at the Weiss hearings, but that financial statements were collected from the investigators soon after the subjects were recruited for the Phase II trial. A report of that study, published this year in the 9 March issue of the *New England Journal*, noted that 8 of the 34 principal investigators held stock in or did consulting work for Genentech. He says none of those involved in data collection during the course of the study had financial interests in Genentech. Besides, he says, there was no question of conflict of interest because that phase of the study focused on angioplasty, and all the patients got TPA.

Nonetheless, says Healy, "TIMI made everybody sensitive." Her group actually started discussing the conflict of interest issue last spring, at which time she says several of the investigators held stock in Merck or Du Pont, two of the companies supplying drugs for the research. "Everybody bought into the guidelines," she says. They affect about 30 investigators in the study, which is a 7-year, multicenter trial of lipid-lowering therapy on patients who have had coronary artery bypass surgery.

In the same issue of the *New England Journal*, editor Arnold Relman applauded the guidelines as an important step for dealing with "the growing entrepreneurship among clinical investigators." But, he said, "a broader and more institutionalized approach is needed."

At the Weiss hearing, officials from the National Institutes of Health (NIH) defended their policy, which requires investigators to comply with whatever safeguards are in effect at their institutions. But since then they have been talking about more specific guidelines. On 20 January, NIH issued a notice that it "expects" investigators not to have financial interests in organizations whose products are the subject of study. A public meeting is planned on 27 and 28 June where researchers, lawyers, and representatives from industry will discuss various proposals. According to William Goldwater of the NIH extramural research division, some people think a flat ban on stockholding is going too far and that compromise measures, such as prohibiting the buying or selling of stock during the course of a trial, may be preferable.

Meanwhile, Weiss is planning another hearing on scientists and conflicts of interest to be held before the end of June.

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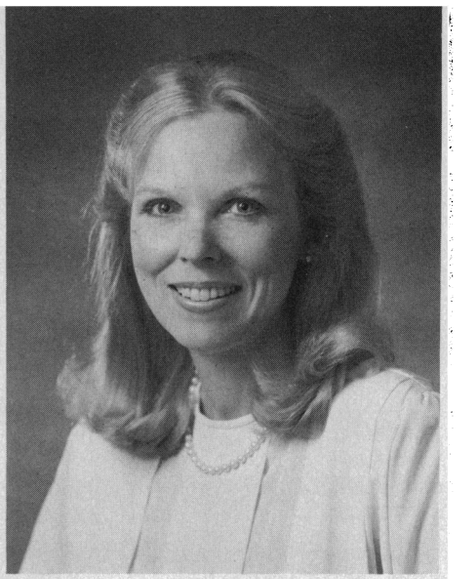
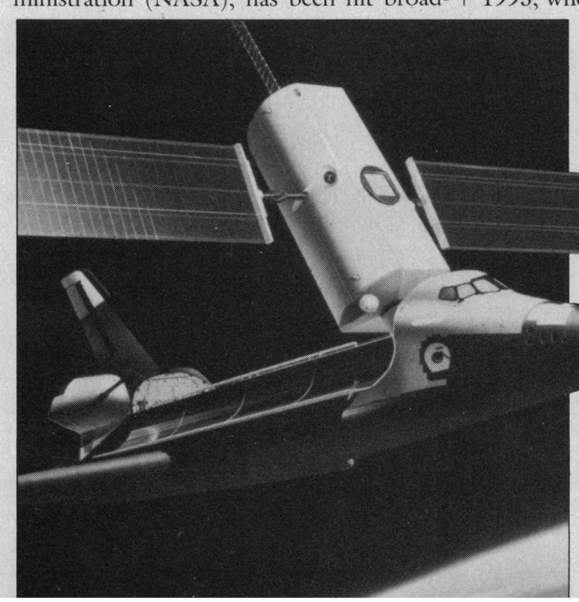


Bernadine Healy: *"Everybody bought into the guidelines."*

National Academy Panel Rejects the Case for a Mini-Space Station

A mini-space station, the focus of a widely trumpeted Reagan initiative last year and a rival to the big international station planned by the National Aeronautics and Space Administration (NASA), has been hit broadside by a negative expert review.

The review, run for NASA by the National Research Council, declared on 11 March that the mini-station will not be needed by 1993, when it was meant to go aloft. There are not enough specialized low-gravity experiments or industrial projects waiting in line to justify such a vehicle, the reviewers find. However, the experts did not examine the justification for the big station with similar rigor, nor did they examine the likelihood that the big proj-



Mini-Station: No need? *Experts find no reason for the government to lease a research lab backed by Space Industries Inc. of Houston.*