

NIH Grapples with Conflict of Interest

While Congress looks on, NIH officials are trying to devise guidelines on what constitutes acceptable behavior

Ethics In Science

WHETHER SCIENTIFIC CONFLICT of interest is a pervasive problem or merely the flavor of the month for an issue-hungry

Congress, the National Institutes of Health is trying to show that it takes the question seriously. At a 2-day meeting on 27 and 28 June, NIH, together with the Alcohol, Drug Abuse and Mental Health Administration, listened to perspectives from industry, academic and independent research institutions, and government officials with the aim of spelling out appropriate behavior for scientists receiving federal funds for research.

NIH has good reason to take the issue seriously. If it doesn't, some members of Congress are threatening legislation.

In just the past year, several events have caught the interest of Congress. At Harvard University, researchers were accused of holding up negative results about an eye medication that was to be sold by a company in which they had a financial interest; and participants in a multicenter clinical trial of thrombotic therapy had a financial interest in the company that made one of the drugs being studied.

In January, NIH signaled its plan to head off such problems when it announced in the NIH Guide for Grants and Contracts that "NIH expects that participating investigators and consultants will not have financial interests in organizations or entities that produce drugs, devices, or other interventions studied in a [Public Health Service-sponsored] controlled clinical trial."

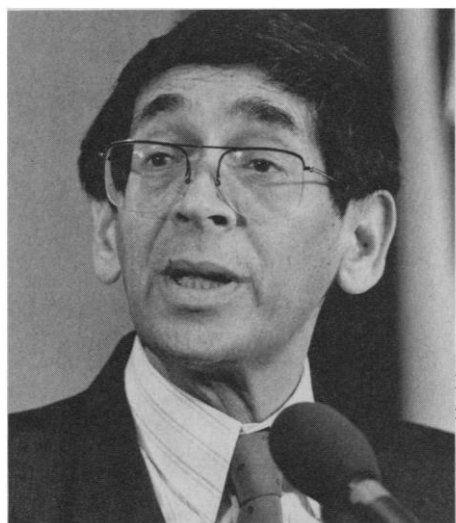
But conflict of interest, like pornography, tends to defy simple definition: one researcher's conflict of interest is another's mutually beneficial working relationship. As if to underscore the difficulty in determining what is an appropriate relationship between commercial and academic research, there were several references to the so-called "snicker test." First mentioned by Diana Zuckerman, a staff member on Representative Ted Weiss' (D-NY) subcommittee on human and intergovernmental relations, the snicker test is failed when a researcher's

relationship to a company draws snickers from the audience when described as being free from conflict of interest.

Some have attempted more concrete methods of determining or eliminating conflict of interest. Bernadine Healy of the Cleveland Clinic Foundation published a statement in this year's 6 April issue of the *New England Journal of Medicine* that no one participating in a large clinical trial of anti-cholesterol drugs that she heads would have any financial ties to the companies that manufacture the drugs. Financial ties would include buying, selling, or holding stocks in one of the companies or acting as a paid consultant for the company. Healy argued that such restrictions would eliminate any taint to the study's conclusion.

But others see Healy's position as unnecessarily restrictive. Paul Lietman, a clinical pharmacologist from Johns Hopkins University, argues that long-term consultancies with pharmaceutical companies provide researchers with information that will help them design trials. Lietman says that even during the study of a particular drug a paid consultancy is legitimate so long as the study is constructed in such a way as to eliminate investigator bias.

The nature of the financial tie between a



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university researcher and a commercial company can also determine whether the relationship is acceptable. Johns Hopkins University permits paid consultancies for its faculty, but a researcher may not hold an equity interest in a company that supports his research.

The University of California has extensive reporting requirements for researchers receiving funds from nongovernment sources. But if California's experience is at all typical, the problem of unacceptable conflicts of interest is a relatively small one. Belle Cole from the UC system told the conference that in reviewing some 28,000 statements of outside support over the past 7 years, the university found only seven to be inappropriate.

While universities appear willing to take the question of conflict of interest seriously, there is a fear that Draconian regulations may be imposed that will stifle research. David Korn, dean of the Stanford University Medical School, says that Stanford's policy relies heavily on the integrity of individuals. "Faculty in universities are a very unregulatable bunch of people by tradition, so that whenever somebody tries to impose a set of new requirements faculty are extremely suspicious and unwilling to go along."

Korn drew applause from the conference participants when he criticized Representative Weiss's zeal for investigating conflict of interest charges in universities, since his own organization has been accused of harboring special interests.

If there was anything resembling a consensus about how conflict of interest might be avoided, it was in the suggestion that complete disclosure of financial relationships should be spelled out. It seemed equally clear that institutions receiving federal funds will have to take a leading role in ensuring full disclosures and establishing procedures to deal with conflicts.

As the conference closed, Katherine Bick, NIH deputy director for extramural research, promised that NIH would develop guidelines that will be available for public comment, by the summer's end, defining the scope of and standards for conflict of interest policies, procedures for disclosure, and possible sanctions.

But Weiss, who did not attend the conference, was clearly not satisfied by the way the conference concluded. "Based on reports of the 2-day meeting," he said, "it appears that the academic community is more concerned about maintaining the status quo than it is with minimizing bias in research. Unfortunately NIH seems reluctant to provide the necessary leadership. I am concerned that the only solution may be a legislative one."

■ JOSEPH PALCA