

## CONFLICTS OF INTEREST

**WILL RESEARCH SUCCESS INCREASE RISK OF BIAS?**

WASHINGTON, D.C.—Because of their growing potential for commercial payoffs, federally sponsored biomedical research programs are coming under sharp scrutiny. Borderlines between basic and applied commercial research have blurred, raising concerns that increased numbers of researchers are facing both real and perceived conflicts of interest. These concerns are prompting officials at the National Institutes of Health (NIH, Bethesda, MD) to draft new guidelines redefining conflict of interest and recommending how to avoid it. Current views that will help mold these guidelines were aired during a "Conflict of Interest Forum" sponsored by NIH in late June.

The conflict-of-interest topic is riddled with confusion, paradoxes, and apparent conflicts of intent at the federal policy level. Academic researchers who depend on federal agencies such as NIH for support must have ample freedom to be innovative, says Katherine Bick, NIH Deputy Director for Extramural Research. Yet whenever possible, their research must be "useful to all the population." Thus, Congress has mandated several technology-transfer programs during recent years that encourage close collaborations between academic and corporate researchers. Such programs inevitably tend to put researchers into positions of perceived, if not actual, conflict.

It is a "clash of two cultures—the scientific and legal," says David Korn, Dean of the School of Medicine at Stanford University (Stanford, CA). The "commercial potential of the new biology" is changing the scientific culture within universities, he says. Nonetheless, academic settings have traditionally provided "a unique relationship between the federal government and universities...[that is] a largely self-governed system...of [federal] investment," he says. At Stanford, full disclosure of financial commitments helps to provide safeguards, but the nature of current biomedical research makes it difficult—if not impossible—to preclude faculty involvement in commercially relevant biomedical research projects.

Perhaps the most serious general concern is whether a "financial conflict of interest...will bias studies," Bick says. Concerns are particularly noticeable when the stakes are high, such as when large-scale clinical studies are undertaken in the course of bringing new pharmaceutical products before the Food and Drug

administration (FDA) for marketing approval. Allegations have been made, for example, that key clinical investigators testing Genentech's (South San Francisco, CA) tissue plasminogen activator (t-PA) had "financial holdings" and therefore would benefit personally following FDA approval of the product, she notes. "In doing large-scale clinical studies, which can't be replicated easily because of their size, we'd like to...guarantee there is no biasing of results."

"There is a growing consensus that clinical trials need special treatment," says Diana Zuckerman, a staff member of the House Subcommittee on Human and Intergovernmental Relations, which has convened several hearings investigating potential conflicts in biomedical research. Like Bick, Zuckerman cites allegations about the t-PA trials, asserting that researchers with stock holdings may have delayed publication of data about side effects. Perhaps there should "be no stock holdings" among key academic investigators conducting such trials, she says. Because "financial interests can have an influen-

ce...maybe just the appearance [of conflict] must be dealt with."

"Safeguards" are needed, and thus it may be "prudent and appropriate for principal investigators not to have a financial interest" in the outcome of clinical trials they are directing, agrees Bernadine Healy of the Cleveland Clinic Foundation (Cleveland, OH). She urges the development of "specific guidelines" so that investigators "know ahead of time what's expected." She also recommends classifying research into several categories, including basic, small-scale, and large-scale clinical trials, each with "safeguards tailored to potential biases." Such recommendations are "intended to clear up the [current] atmosphere of distrust."

Nowadays, the "very best and brightest faculty members are increasingly involved" in projects that have direct commercial implications, adds Stanford's Korn. "Cases are being brought to us voluntarily by scientists of integrity...The solutions require a high degree of customization—not simple generic prescriptions." —Jeffrey L. Fox

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