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Cosmic pollution zone

FINANCIAL CONFLICT

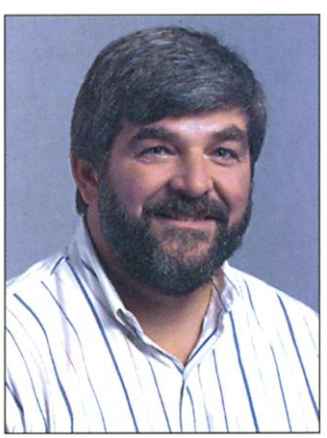
Universities Puncture Modest Regulatory Trial Balloon

Even the blandest words can be incendiary when they're about money. U.S. officials have learned that lesson the hard way this winter after the chief lobbies for academic medicine kicked up a fuss about suggestions on how to deal with financial conflicts of interest. Their opposition is likely to shoot down a mildly worded "draft interim guidance on financial relationships in clinical research" issued by the Department of Health and Human Services (HHS) in January.

The HHS rule-writing effort was designed to tune up policies that were last examined in 1995. The current push began after a young man died in a university-based gene therapy experiment in 1999. The case drew attention because one of the clinicians in the project, and the academic institution itself—the University of Pennsylvania—had equity in a company that was hoping to benefit from the research (*Science*, 12 May 2000, p. 954). But the cry for clear and consistent new standards regarding money and medicine, led by former HHS Secretary Donna Shalala, so far has failed to win the attention of the new Bush Administration.

"We haven't issued any guidance yet, and you can't withdraw something that hasn't been issued."

—Greg Koski



The HHS draft guidance (ohrp.osophs.dhhs.gov/nhrpac/mtg12-00/finguid.htm) reflects what officials saw as a consensus on how to deal with the increasing role of industry in academic medicine. Among other things, it suggests that researchers' potential conflicts be disclosed to the same Institutional Review Boards (IRBs) that now monitor other ethical issues, and possibly to patients as well. About a third of the publicly funded IRBs are considering whether to take a look at financial issues, according to HHS. The draft statement also encourages academics to become involved in reviewing "institutional" conflicts—the kind that occur when a university itself has a financial stake in the outcome of a clinical trial. Drawing on public comments from a meeting last August, the guidance sought to harmonize patchy federal and university policies. It was developed by the new Office for Human Research Protections (OHRP), a high-profile version of an outfit previously housed within the National Institutes of Health.

But even that gentle prodding was too much for academic leaders. The draft is "quite premature," says David Korn, a former dean of medicine at Stanford University who now works on government issues at the Association of American Medical Colleges (AAMC) in Washington, D.C. "I think it is necessary to address these issues," says Korn, but "I don't think the government has any great wisdom [to offer]. We don't even know how to define an institutional conflict of interest."

On 2 March, four major education organizations wrote to OHRP director Greg Koski, asking him to "withdraw" the guidance and "reissue portions of it as points for consideration." They argued that some of the HHS ideas—particularly on potential institutional conflicts—were based on anecdote rather than good evidence. On 8 March, the Federation of American Societies for Experimental Biology echoed those views in a separate letter.

It's not that the community is ignoring the issue. The AAMC, which signed the call for withdrawing the draft along with the Association of American Universities, the Council on Government Relations, and the National Association of State Universities and Land Grant Colleges, is setting up a new panel to formulate its own policy. AAMC president Jordan Cohen is hoping that its 125 member institutions will "agree voluntarily to abide by a common set of principles for managing those conflicts." The panel is headed by William Danforth, former president of Washington University in St. Louis, who has yet to set a date for the first of the proposed twice-yearly meetings.

Koski says he was taken aback by the sharp and "misleading" tone of the response from academia. "We haven't issued any guidance yet," he points out, "and you can't withdraw something that hasn't been issued." HHS published the statement "to start a broad discussion," he adds.

The government and the private sector can work in parallel, says Koski, adding that he hopes HHS can learn from the Danforth committee as it undertakes its review. And he doesn't think it will be too hard to clarify the rules and build public confidence in research: "This isn't rocket science."

—ELIOT MARSHALL

PARKINSON'S RESEARCH

Fetal Cell Transplant Trial Draws Fire

In just 1 week, an experimental treatment for Parkinson's disease—fetal cell transplants—went from promising to perilous. At least, that's how much of the general media reported the publication of mixed results from the first double-blind study. But Parkinson's researchers caution that results from a single trial, especially one that was controversial from the start, should not be the final word on the technique.

On 8 March, neuroscientist Curt Freed of the University of Colorado School of Medicine in Denver, neurologist Stanley Fahn of Columbia University College of Physicians and Surgeons in New York City, and their colleagues reported in *The New England Journal of Medicine* that injecting fetal cells into the brains of Parkinson's patients resulted in a significant improvement in some recipients. Several patients, however, also experienced troubling side effects.