CONFLICT OF INTEREST

Agencies Set Rules on Financial Disclosure

Like a fine wine, some government regulations improve with age. Almost 5 years after the research community rose up to protest what it saw as unduly harsh guidelines to prevent financial conflicts of interest by federally funded scientists, the Public Health Service (PHS) has published a new set of proposed rules that are being roundly applauded for their reasonableness. The proposed PHS rules were issued on the same day that the National Science Foundation (NSF) published comparable, final regulations on the subject.

In September 1989, PHS unveiled proposed guidelines that would apply to researchers funded by the National Institutes of Health (NIH) and other PHS agencies. Three months later, after receiving more than 750 letters running 10-to-1 against the proposal, the agency withdrew the document. Last week PHS showed that it had learned from its mistakes, and scientists demonstrated that they have become more accepting of the idea that financial conflicts of interest are a problem that must be monitored and managed.

"I'm pleased," says Cornelius Pings, president of the Association of American Universities. "Overall, I don't see any great imposition on research." C. K. Gunsalus, associate vice chancellor for research at the University of Illinois, sees them as "a positive example of the process working for both sides. Institutions made comments [on the 1989 proposal], and the agency responded in a thoughtful way."

Like the abortive 1989 guidelines, the proposed regulations for both PHS and NSF, published in the 28 June *Federal Register*, give institutions the primary responsibility for examining researchers' financial holdings for possible conflicts. But that's where the similarity with the original ends. Instead of requiring researchers to disclose all their financial holdings to their institution, the proposed rules limit disclosure to "significant financial interests," defined as holdings worth more than $5000 or more than 5% ownership in a company. And rather than adopting what George Galasso, NIH associate director for extramural affairs, calls a "thou shalt not" approach, the new proposed rules state general aims and leave implementation to the institution.

The PHS proposal provides for 60 days of public comment before officials reconsider the proposal and issue final rules. In contrast, the NSF policy, which was published in draft form in July 1992, is final and goes into effect in June 1995.

While the original NSF draft policy was also controversial—it would have required institutions to turn over researchers' financial disclosures to NSF—NSF's final rule, like PHS's, asks institutions to review the disclosures themselves. The agencies expect institutions to examine federally funded researchers' disclosures annually (NSF estimates that 23% of researchers will have financial interests to disclose) and certify with each federal grant application that they have verified either that no potential conflict of interest exists or that a potential conflict has been "managed." Exactly how to manage potential conflict is again left to the institu-

HOW THE RULES AFFECT YOU

Here's what federally funded scientists must consider under the new rules on potential financial conflicts of interest:

WHAT'S A PROBLEM:
Researchers must disclose to their institutions "all significant financial interests..."

- "...that would reasonably appear to be directly and significantly affected by the research" funded by the agencies, such as salaries, consulting fees, honoraria, and intellectual property rights.
- "...in entities whose financial interest would reasonably appear to be directly and significantly affected" by federally funded research, such as equity in such forms as stocks or stock options.

WHAT'S NOT:
Researchers can withhold from disclosure...

- Financial interests of less than $5000, or less than 5% ownership in a company;
- Income from lectures, teaching, or other services performed for nonprofit entities;
- Ownership in companies applying for Small Business Innovative Research (SBIR) grants. (In the case of those applying to the Public Health Service, the allowance holds only for the first grant.)

WHO'S EXEMPT:
Applicants for NSF grants who work at an institution employing 50 or fewer people.

Scripps Versus Congress, Round II

The Scripps Research Institute is back in the congressional doghouse. The La Jolla, California, institute took a beating last year for a deal with the Sandoz Pharmaceutical Corp. that would have given the company the first fruits of its federally funded research; now it stands accused of failing to disclose that the research behind 43 patent applications was partially funded by the government. The information is contained in a report released last month by the Inspector General of the Department of Health and Human Services, which concludes that the government may be paying unnecessary royalties on Scripps' inventions as well as missing the opportunity to obtain nonexclusive licenses on some products.

An investigation by the Inspector General's office found that Scripps had reported the role of federal funding in just 51 of the 125 patents it had been awarded since a 1980 law required such declarations; 94 of the patents had actually benefited from federal funding. In a 15 June statement, Scripps said that it "became aware last year that it had failed to fulfill all of its reporting obligations," and that it "regrets these past failures." However, it said that it doesn't believe the mistakes had any impact on the government's rights to Scripps' discoveries. Since the investigation, Scripps said, it has worked with the National Institutes of Health (NIH) to establish systems "to ensure full compliance."

The study, requested by Representative Ron Wyden (D–OR), follows an investigation last year by Wyden into Scripps' ties with Sandoz. A May study by the Inspector General revealed that NIH has no systematic process to monitor how grantees report federal funding in their patent applications. Wyden has scheduled a hearing on 11 July to grill NIH officials on their plans.

Last week, NIH issued a primer for research institutions that want to work with industry. Published in the 27 June *Federal Register*, the document expands on the advice given by a special NIH panel earlier this year (*Science*, 4 February, p. 603) on ways to avoid the type of concerns about academic freedom and fair access that were raised by the original deal proposed between Scripps and Sandoz.

–C.A.

tions: The agencies suggest such options as public disclosure, monitoring research with independent reviewers, modifying the research plan, divestiture, and severing a researcher's relationship with the company.

Both NIH and NSF plan to conduct a few random audits each year to keep institutions honest. They also expect tips from whistleblowers to trigger a few more inspections.

Despite an attempt to harmonize the two agencies' regulations, a few differences remain. NSF, for example, exempts researchers at institutions with fewer than 50 employees. "We didn't want to place undue burden on our smaller grantees," says assistant general counsel Micki Leder. But the PHS proposed regulation states that "our experience...indicates that investigators working for small entities may be just as subject to conflict of interest as [those] working for large institutions." PHS has solicited comment on the point, and Leder says that NSF may consider changing its rule if the responses suggest that the 50-person threshold is a mistake.

Likewise, the two agencies disagree on what to do about Small Business Innovation Research (SBIR) grants. This program, imposed by Congress, requires that agencies spend 1.5% of their overall research budget on research and development projects submitted by small businesses. Because a researcher applying for an SBIR grant is assumed to have a financial interest in the company, a conflict of sorts is implicit and there is no need to disclose it, says Leder. PHS, on the other hand, would exempt those who submit SBIR grants only for the first, 6-month phase, a period intended to plan and determine the feasibility of the idea. Once the company applies for a larger, Phase II SBIR grant to actually do the work, its researchers would have to comply with the same regulations as other PHS-funded institutions.

The generally positive response within the research community to the regulations doesn't mean they can't be improved. Research administrators say there's enough they'd like to tinker with to provide PHS with a healthy crop of comments to chew over this summer. PHS is also seeking comments on what to do about issues not specifically covered in its proposal, from institutional conflicts of interest to financial holdings by scientists in companies that compete with products involved in a research application.

David Blake, executive vice dean and vice dean for research at the Johns Hopkins University School of Medicine, is likely to be one such correspondent. Although he's generally pleased with the rules, he thinks researchers should not have to disclose all their financial holdings above the stated threshold; those related to their research should be enough, he argues. "If the faculty aren't able to identify the conflicts in their own research, then the whole system is in trouble," he says, adding that unnecessary and intrusive rules tend to breed noncompliance.

But compared to 1989, when Blake was among those objecting the most loudly to the proposal, such concerns are secondary. "We can fundamentally live with it," he says, adding that reasonable rules should make it easier for institutions to craft common policies for compliance. As they say, time heals all wounds.

–Christopher Anderson

1995 BUDGET

Station's Survival Could Cramp Science

Last week, what promised to be a tough congressional fight over the fate of the space station turned into a rout: Supporters in the House of Representatives clobbered an amendment to kill the project, 278 to 155. But the station's good fortune could come back to haunt science, which has so far been trimmed but not badly cut by Congress. The Senate, which has traditionally been an even stronger supporter of the station than the House, allocated some $300 million less to the subcommittee that handles the National Aeronautics and Space Administration's (NASA's) budget, which means the subcommittee may end up cutting research programs at NASA, the National Science Foundation (NSF), and the Environmental Protection Agency to pay for the station.

Congressional aides credited the space station victory to an all-out lobbying effort by the Administration, led by Vice President Al Gore and NASA administrator Daniel Goldin. They stressed the foreign policy advantages of NASA's collaboration with Russia on the project, arguing that employing Russian space scientists keeps them out of the clutches of current or potential nuclear powers such as India, Iraq, and North Korea.

Station supporters were also blessed with a misguided attempt to kill the project. In an effort to gain the support of scientific groups, Representatives Tim Roemer (D–IN) and Dick Zimmer (R–NJ) proposed returning the $2.1 billion requested for the station to NASA, rather than using it for deficit reduction. But the move backfired. Budget hawks didn't want to spend the money at all, and scientific groups, unlike in past years, refused to criticize the station.

The debate now moves to the Senate, which is expected to take up the NASA budget this month. Although the station is considered relatively safe there, the smaller Senate budget allocation could spell trouble for NSF, which is funded by the same appropriations bill. Senator Barbara Mikulski (D–MD), chair of the subcommittee that oversees that bill, will be hard-pressed to match what the House did last month: a 2.5% increase for research ($53 million more instead of a requested boost of $185 million) and 3% for education (matching the $17-million requested increase).

Other research agencies are not in such direct competition with the station, because they are handled by different appropriations subcommittees. But they are nevertheless getting squeezed. The National Institutes of Health (NIH), for example, can look forward to an increase of about 3.5% if the Senate follows the House's lead. Last week the House passed a bill that would raise funding for NIH from $10.9 billion in 1994 to $11.32 billion in 1995—$150 million short of the President's request.

For high-energy physicists, the Senate's action last week on the Department of Energy's (DOE's) budget contains mixed news. The Senate killed construction funds for the proposed $3-billion Advanced Neutron Source (ANS) at Argonne National Laboratory, citing an uncertain cost and concern that the design is "not mature." This, along with a House decision to delete all but $10 million for ANS construction, could delay the project for at least a year.

The situation is even more muddled for the proposed Tokamak Physics Experiment (TPX) at the Princeton (New Jersey) Plasma Physics laboratory. Senator Bennett Johnston (D–LA), chair of the energy appropriations subcommittee, wants a federal commitment on the proposed International Thermonuclear Experimental Reactor (ITER) before he will support TPX. Although he agreed to an amendment from the New Jersey delegation to reinstate $45 million in construction money, the deal is contingent on passage of an authorization bill proclaiming the nation's commitment to ITER. Such a bill has already passed the Senate, but a much different version is before the House.

The biggest research-related winner so far is the National Institute of Standards and Technology (NIST). Its Advanced Technology Program received $232 million of its $252-million request in the House, bringing the program to $431 million. The Defense Department's $243-billion budget, passed in 15 minutes before the House recessed for the July 4th holiday, retains a $900-million cut in funding of university research (*Science*, 1 July, p. 23), but the lack of debate on the normally contentious bill is seen as a sign that the cuts will be restored in the final bill.

–Christopher Anderson, Eliot Marshall & Jeffrey Mervis