NIH Conflict-of-Interest Guidelines Shot Down

The first attempt to draw up standards of behavior was less than a success, but NIH officials vow to try again

FACED WITH A FIRESTORM of protest, the Public Health Service has retreated from the controversial guidelines it proposed last year to guard against conflicts of interest in federally funded research. On the last working day of 1989, Secretary of Health and Human Services Louis W. Sullivan sent the National Institutes of Health back to the drawing board to come up with a new set of proposals "that properly treat potential abuse while keeping the research process free of unnecessary burdens and disincentives."

The Secretary's decision brought broad smiles to a loose coalition of universities, biomedical research companies, venture capitalists, and research scientists who wrote letters, visited members of Congress, and lobbied officials throughout the executive branch to kill the guidelines on grounds that they were unnecessarily burdensome and might even harm U.S. industrial competitiveness. The protesters have won a battle, but not necessarily the war. Says Richard D. Godown, president of the Industrial Biotechnology Association: "I don't think that the concept of the guidelines has gone away. I just think these [particular] guidelines have gone away."

Last year, congressional interest in the issue convinced NIH it had to take on the question of conflict of interest. In June, NIH, along with the Alcohol, Drug Abuse and Mental Health Administration, held a 2-day workshop to discuss the ethical, legal, and administrative issues involved in establishing appropriate rules to govern conflict of interest (*Science*, 7 July 1989, p. 23). While there was some annoyance directed at NIH for feeling it had to tackle the question in the first place, the real animosity at the meeting was directed at Representative Ted Weiss (D–NY), who had earlier held hearings on the subject of conflict of interest. Many felt that Weiss, despite having uncovered examples of questionable arrangements between industry and federally funded researchers, was trying to make political hay out of a few isolated incidents.

When NIH published its guidelines in the 15 September edition of the *Guide for Grants and Contracts*, Weiss was generally pleased, but researchers were aghast (*Science*, 29 September 1989, p. 1440). Over the 90-day comment period that ended 15 December, NIH received nearly 700 letters, running more than ten to one against the guidelines as proposed.

The complaints focused on several areas. Many felt they would subject researchers to overly burdensome financial disclosure requirements. According to an analysis by Susan L. Charrier, administrator of the Fred Hutchinson Cancer Research Center, even a relatively small institution like hers would have to set aside 4.3 feet of file space each year just to hold the financial information.

Others complained that the guidelines were unacceptably vague about what constitutes a conflict of interest. Many criticized the guidelines' "prohibited situations" which would have barred researchers from having a financial interest in "any company that would be affected by the outcome of [their] research." How, some wondered, could you know in advance exactly which companies might express an interest in a basic research project?

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Getting guidance. *NIH deputy director Katherine Bick got plenty of advice on improving NIH guidelines.*

The guidelines would also have prohibited researchers from taking any money from companies whose products or services they were evaluating in a federally funded project. Clinical researchers, notably several representatives of the NIH-sponsored AIDS Clinical Trials Group, pointed out that ties with industry were crucial for rapid progress. An individual's bias, they argue, could hardly be a major factor in influencing the outcome of rigorously controlled multicenter trials.

Among the loudest complaints were those from biotechnology companies, who said the guidelines would stifle transfer of technology from federally sponsored research to the private sector—something the government has long been saying it wanted to increase.

The overall response to the guidelines was instantaneous and vehement. Those opposed to the guidelines mounted a full court press to dump them, going over NIH straight to the secretary. Presidential science adviser D. Allan Bromley and his deputy James B. Wyngaarden—former director of NIH—were also called on for help, as were top officials in the Commerce Department. Their protest did not fall on deaf ears, partly because, as James O. Mason, head of the Public Health Service says, Sullivan "is obviously concerned about anything that would have a chilling effect upon the nation's biotech industry."

But the NIH has not given up. Katherine Bick, deputy director of NIH for extramural affairs, whose office wrote the guidelines, says NIH has an obligation to tackle the conflict-of-interest issue. She says although individual scientists have the ideas that fuel technology transfer, they are not the ones who must determine how that process can proceed.

Bick says NIH remains committed to coming up with some form of guidelines. Secretary Sullivan has now stated that the guidelines will appear as formally proposed rules in the *Federal Register* rather than the less formal guidelines NIH had proposed. "I never had any illusions that this was not going to be changed," says Bick. "The plan has been all along to work with what we get in." Mason adds that the responses NIH has received so far will help shape the next iteration of the guidelines.

For his part, Representative Weiss also expects the HHS to try again. He says he could live with the possibility of excluding basic researchers from the guidelines and focusing more on researchers whose work is more closely related to commercial products. But Weiss adds that the problem of conflict of interest is real and needs to be addressed: "If [Sullivan] is taken in by the people in the biomedical research community who say there is no problem, that's a terrible misstep on his part."

■ JOSEPH PALCA

Some of the Voices from the Chorus of Protest

The following are excerpts from the approximately 700 responses the National Institutes of Health received concerning the proposed NIH/ADAMHA conflict-of-interest guidelines. Since the excerpts are all drawn from longer letters commenting on the guidelines, they are intended only to characterize the spectrum of opinion on the subject. Affiliations are listed for identification only, as many of the authors wrote as individuals, not as representatives of any institution. ■ **J.P.**

"The proposed guidelines are inoperable, are an affront to the personal integrity of the vast majority of scientists, are an invasion into the private lives of multitudes of individuals, are a bureaucratic nightmare attempting to obtain information that will most likely be withheld anyway, and will significantly impact the current interactive environment that has been nurtured by so many to establish close ties between academia and industry for the successful development of beneficial products, therapies, and diagnostics." **Susan L. Charrier, administrator, Fred Hutchinson Cancer Research Center.**

"The proposed NIH 'conflict-of-interest guidelines' would be draconian in their potential deterrent effects upon technology transfer from universities and government laboratories. . . . [They] are an overreaction to a very small number of real but deplorable and possibly criminal instances of abuse. *Existing laws and institutional rules already cover such cases.*" **D. Bruce Merrifield, vice president for research and development, Greater Minnesota Corporation.**

"There are those in Washington who live with the quaint notion that by burying us, quite literally, under mountains of paperwork, increasingly palpably every year, I and my colleagues are able to think more clearly and creatively about our science." **Robert A. Weinberg, member, Whitehead Institute.**

"I recognize that the proposed regulations address a serious concern: the integrity of the scientific process. . . . Nevertheless, there is considerable agreement within Massachusetts's research community that the regulations as proposed will cut off most or all relationships between emerging technology companies and academic researchers." **Michael S. Dukakis, governor, Massachusetts.**

"We support NIH's initiative in taking steps to curb conflicts of interest in NIH-sponsored research, but we believe the proposed guidelines do not go far enough toward achieving that goal. Accordingly, we urge NIH to make the conflict of interest restrictions binding on all grants and contract recipients. **Patti A. Goldman, staff attorney, and Sidney M. Wolfe, director, Health Research Group, Public Citizen.**

"The proposed policy is a classic case of overkill and two steps back for one step forward." **Mitchell Litt, professor, University of Pennsylvania School of Engineering and Applied Science.**

"As a principal investigator of a community clinical oncology program, I feel this entire suggestion is absolute balderdash." **John A. Ellerton, Southern Nevada Cancer Research Foundation.**

"In most instances, private interest and public interest can coincide without interfering with the objective conduct of publicly funded research, and the guidelines should recognize that fact." **Gerald J. Mossinghoff, president, Pharmaceutical Manufacturers Association.**

"The proposed guidelines are a step in the right direction. . . . I have seen firsthand what happens when fellow faculty members, department chairmen, deans, and vice presidents of a university have a vested interest . . . in promoting an entrepreneurial venture of another faculty member supported to a significant extent with NIH funds." **Kenneth B. Sloan, associate professor of medicinal chemistry, University of Florida College of Pharmacy.**

"In general, I support the thrust of the guidelines. . . . The public welfare would not be well served if the majority of biomedical investigators had business interests involving the work they are doing." **Arnold S. Relman, editor-in-chief, *The New England Journal of Medicine*.**

"The cruel irony is that these 'Proposed Guidelines' come at a time when Congress, the Administration, and the Public are pushing for a closer cooperation between the NIH, academic research, and companies." **Brook H. Byers, Kliener, Perkins, Caulfield & Byers, venture capitalists.**

"We ask that the NIH/ADAMHA, in developing its next iteration of this proposal, further define which situations may truly compromise the credibility and quality of federally funded research and design clearer and more specifically targeted approaches to dealing with those situations." **Robert G. Petersdorf, President, Association of American Medical Colleges.**

"I have found it impossible to conjure up effective measures that would protect us against conflict situations other than to continue to depend on individual integrity and to introduce policies and procedures of full and timely disclosure. To go beyond that point, in my judgment, is futile and will accomplish little else other than to stifle research creativity and rapid transfer of the fruits of that research to the public benefit." **David Korn, vice president and dean, Stanford University Medical Center.**

"The National Institutes of Health Proposed Guidelines for Policies on Conflict of Interest . . . interject an important counter-measure to the otherwise uninterrupted trend toward greater secrecy and less accountability in the use of federal research monies." **Jaron Bourke, director, Harvard Watch.**

"The U.S. is dominant in biotech and medical device technology while other areas of technology have been slipping away from us. Are you trying to kill the goose that laid the golden egg?" **Frederick K. Fluegel, Matrix Partners, venture capital firm.**

"I believe that the proposed guidelines are sound and that they serve the public's interest in making scientific findings paid for by public monies equally available to all members of the public." **Arthur L. Caplan, director, Center for Biomedical Ethics, University of Minnesota.**

"Not the least of our objections is the insidious assumption that seems to underlie the guidelines: that the university biomedical research community is motivated primarily by venality and is incapable of effective self-regulation. This arrogation of guilt has generated a policy that is unnecessarily intrusive, restrictive, and administratively burdensome." **Karl J. Hittelman, associate vice-chancellor, University of California, San Francisco.**