NATIONAL INSTITUTES OF HEALTH

Panel Proposes Guidelines for Industry

For more than a decade, the government has encouraged research institutions to strike deals with industry to turn federally funded science into commercial products. But last year, after the Switzerland-based Sandoz Pharmaceutical Corp. agreed to pay Scripps Research Institute $300 million over 10 years for exclusive rights to exploit what was expected to be more than a billion dollars' worth of taxpayer-funded research, some members of Congress decided that reforms were needed to keep institutions from giving away the store (*Science*, 25 June 1993, p. 1872).

Last week the National Institutes of Health (NIH) took its first formal steps to appease Congress by asking an ad hoc panel of academic and industrial scientists and research administrators to recommend guidelines for institutions drawing up future deals with industry. NIH has promised Representative Ron Wyden (D–OR), who chairs a House subcommittee that oversees regulation of small businesses, that it will craft such guidelines by June, and officials hope the results will be substantive enough to please Congress without being a hindrance to companies and research institutions.

NIH officials don't want to play cop: Their job is to fund biomedical research, they say, not regulate the biotech industry. "We're not the FDA," one says. NIH has traditionally been willing to screen proposed agreements for institutions that seek advice, but Steven Jenning, a Wyden aide, says that "we don't think a voluntary system provides sufficient protection." Wyden wants NIH to issue guidelines and set a threshold above which agreements must be submitted to NIH for review and approval, but the panel was asked to consider only the content of possible guidelines, not their authority.

After 2 days of heated discussion that included repeated warnings not to tamper with a system that's working well, the panel concluded there was indeed a need for guidelines on some agreements covering research funded by a combination of government and industry. In particular, it recommended that deals of "unusual" scope and size—typified by agreements where the industrial partner is contributing at least $5 million per year, $50 million total, or more than 20% of total funding to an NIH-funded institution—conform to the following standards:

■ **Research Freedom:** Participation by NIH-funded principal investigators in research covered by the corporate agreement should be voluntary, with their written consent. The right to scientific communications, including publication, should be protected, and there should be no restrictions on their future scientific activities.

■ **Fair Access:** The industrial partner should have a "one-shot, limited time" option to commercialize research covered by the agreement. The option should be on an invention-by-invention basis rather than covering an entire area of research, and the partner should have a limited period to decide which research to claim before allowing other companies access. No sponsor should have the right to reclaim research it had earlier rejected if another company expresses an interest in it.

■ **Utilization:** Corporate partners should be required to exercise "due diligence" in commercializing a product and should not be allowed to simply lock up research to deprive other companies of access.

■ **U.S. Manufacturing:** A 1980 law gives preference to companies that plan to manufacture in the United States the products of government-funded research. But the panel recommended that other considerations, such as a company's U.S. research investments and nonmanufacturing jobs, also be considered.

The promise of proposed guidelines within a year was made last June by then-NIH Director Bernadine Healy when she testified before Wyden's subcommittee. That task now falls to her successor, Harold Varmus, who said the advisory panel's recommendations will be one of several inputs.

–Christopher Anderson

JAPAN

ERATO Grows Beyond Its Borders

TOKYO—When the Japanese government launched the ERATO program in the early 1980s, it set out to break the mold of traditional university research by focusing on relatively risky projects built around the work of individual scientists rather than academic departments. Now, the ERATO (Exploratory Research for Advanced Technology) program is breaking its own mold: It recently launched its first project to be based outside Japan—research on quantum optics headed by physicist Yoshihisa Yamamoto at Stanford University. And a spinoff ERATO program is about to fund a large-scale cooperation between researchers at Tokyo University and the University of California (UC), Santa Barbara, Center on Quantum Structures. Both moves extend what Genya Chiba, ERATO's founder and director, calls the "internationalization of ERATO" and are part of a continuing effort by Japanese officials to counter criticism that its scientists take in more than they share in the global interchange of research.

MARK STACKY

Pacific link. QUEST director James Merz *(seated left)* watches UC chancellor Barbara S. Uehling sign cooperation agreement.

Yamamoto, who previously worked at Nippon Telegraph and Telephone Corp., has been a professor at Stanford University since 1990. After getting favorable reviews of Yamamoto's work in semiconductor lasers and quantum optics, Research and Development Corp. of Japan (JRDC) officials decided last summer to award him about $17 million in funding over 5 years for work on quantum fluctuations of semiconductor laser light. His goal is controlling the movement of single electrons and single photon emissions in nanometer-scale semiconductor devices.

The second California collaboration, which will be celebrated next week at Santa Barbara, grows out of long-time professional ties between Hiroyuki Sakaki of Tokyo's Research Center for Advanced Science and Technology and James Merz, director of the Center for Quantized Electronic Structures (QUEST) at UC Santa Barbara. In 1992, during Merz's most recent sabbatical in Japan, the two decided to seek more formal links between their labs, which are studying the physical properties of nanostructures with the goal of making very high-speed integrated circuits and microscopically small lasers. So each appealed to the government source of their research funding.

JRDC, which spends $85 million a year on 37 ERATO projects (*Science*, 23 October 1992, p. 586), responded enthusiastically, agreeing to fund the Japanese side of the effort through its International Joint Research program. Sakaki, who has just com-

pleted an ERATO project on a related theme, is assembling a fresh team for the new project, which will receive $9 million over 5 years to send a stream of researchers to Santa Barbara for visits of varying lengths. The National Science Foundation (NSF), which already gives QUEST $2.7 million a year as one of its 25 science and technology centers, is still evaluating a request from Merz for $1.1 million over 5 years to send U.S. scientists to Sakaki's lab. NSF has, however, endorsed the collaboration, and Merz is optimistic that, one way or another, he will find the money to send members of his team to Tokyo.

The collaboration will strengthen both research teams, says Merz. The Japanese will gain access to such U.S. facilities as the free-electron laser facilities at Santa Barbara, while U.S. researchers will be offered use of special semiconductor processing equipment and high magnetic field facilities available in Tokyo. And there is also the human element. "Once you have a collaborative project, you are forced to sit and talk for a long time," says Sakaki.

This project is the fifth international collaboration supported on the Japanese side by JRDC. Since 1990, JRDC has provided money for joint work with researchers at NSF's Center for Microbial Ecology at Michigan State University, a group of British universities working on atomic structures, a team at France's Louis Pasteur University working on supermolecules, and work on new radioassays to track subfemtomole biological processes with a group at Uppsala University in Sweden.

After participating in a ceremony on 9 February in Santa Barbara, JRDC officials will travel to Palo Alto to kick off the Yamamoto project officially. More foreign sites may be chosen, says ERATO administrator Hiroo Uchino, because of growing interest in the program from non-Japanese scientists. Chiba, a JRDC vice president, sees both programs as a product of global trends. "Things are getting more borderless," he says.

–Dennis Normile

Dennis Normile is a freelance writer in Tokyo.

SCIENCE POLICY

A Strategic Message From Mikulski

Last fall, Senator Barbara Mikulski (D-MD) shook up the scientific community by telling the National Science Foundation (NSF), a bastion of support for academic research, that 60% of its budget should be spent on "strategic" research aimed at meeting national needs (*Science*, 17 September 1993, p. 1512). Researchers jumped to the conclusion that she wanted NSF to reallocate its $3 billion budget away from supporting the best fundamental research and into areas promising a swift and more certain payoff for society. On Monday, Mikulski, who chairs the appropriations subcommittee that funds NSF as well as space and environmental science, went some way toward soothing researchers' fears. She told 300 top scientists and research administrators that her vision of NSF isn't all that different from theirs. And she went on to describe two threats to academic science that she considers more worrisome: budget-cutting colleagues who see basic research as a tempting target, and a public that doesn't understand how research benefits the nation.

"I understand science, and I think we should continue to do what most delights scientists—the wonder of discovery," she said. "But the techno-cutters are out in force. And they can [cut basic research] with the full knowledge that they aren't taking any of the benefits of a single disabled veteran, or a single shelter for the homeless, or a single school lunch. To fight them, we need to articulate a vision for science and where it is going." But then she added the kind of statement that makes scientists nervous: "And that means a fundamental reevaluation of how NSF does business."

Mikulski was one of several speakers on the first of 2 days of a government-sponsored forum entitled "Science in the National Interest" (*Science*, 14 January, p. 165). The forum, held at the National Academy of Sciences, was organized by biologist M.R.C. Greenwood, the chief scientist in the White House Office of Science and Technology Policy (OSTP), to give those with a stake in federally funded research—from academia, industry, and government—a chance to comment on how to achieve the Clinton Administration's goal of achieving world leadership in science, mathematics, and engineering. Their comments will be passed along to top federal science officials, who will draft a white paper on science policy that parallels the Administration's statement on technology issued early last year (*Science*, 26 February 1993, p. 1244).

RICK KOZAK

Your goals are my goals. Senator Mikulski.

The phrase "strategic research" was never meant to be a straitjacket, Mikulski explained. Rather, it is intended to help legislators understand how science can help the country win the global economic war in the same way that national security provided a rationale for supporting science during the Cold War, Mikulski said. "It's like sailing on the Chesapeake [Bay]," she explained. "You zig and zag, of course, but you're always moving with respect to a navigational map."

Mikulski recommended one major new tack for NSF in this zig-zag course: She suggested that the foundation's top officials should consider an internal realignment to emphasize the link between what it funds and the national need being addressed. "NSF is organized like a university, with directorates for biology, geoscience, and mathematics and the physical sciences," she said. "Maybe it's time to reorganize into a series of institutes on manufacturing, global change, high-performance computing, and other strategic areas." The best model for strategic research is the National Institutes of Health (NIH), she said. "NIH is grouped around diseases—which are strategic opportunities that touch everybody's life—and it's no coincidence that we have the National Cancer Institute, not the National Institute of Molecular Biology." In response, NSF officials noted that the foundation has revised its structure several times over the years to meet new challenges but that the goal of funding the best people and the most promising research has not changed.

Reaction to Mikulski's comments from the participants was generally positive, with many welcoming her call for change. "She's telling us that we have to do a better job explaining ourselves," interprets NSF Director Neal Lane. "And she's right." But there was a pervasive feeling among most researchers at the meeting that the system is not broken and doesn't need to be fixed.

University of Michigan chancellor James Duderstadt, who chairs the National Science Board (NSB) that oversees NSF, says he would like to play a tape of Mikulski's speech to his faculty and others around the country. "I don't think it would reassure them, but I think they need to understand what people are thinking in Washington, and that it's no longer business as usual."

–Jeffrey Mervis