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-