NIH Scientists Agonize Over Technology Transfer

Once an island of pristine research, NIH investigators now use words like "venture capital" and "proprietary information"

LIKE SHY BUT COMELY debutantes, scientists at the National Institutes of Health are fretting over how to respond to the advances of their suitors in industry. Unlike their more worldly peers in the universities, the government researchers are just now beginning to wrestle with the ethical dilemmas posed by entry into the entrepreneurial arena, a place very different from the sheltered enclave of NIH.

The government scientists are being introduced into these new relationships because of the Technology Transfer Act of 1986, which mandates the creation of official partnerships between federal laboratories and the private sector. The point of the law is to exploit the government's investment in research by encouraging government scientists to help get their products into the marketplace, and thereby give a leg up to American competitiveness. Until recently, the government's engineering labs seemed much more interested in technology transfer than the nation's biomedical enterprise. But that is beginning to change.

After almost 2 years of negotiations, the first of these official partnerships at NIH was signed in April between a small start-up company called Genetic Therapy, Inc., and W. French Anderson of the National Heart, Lung, and Blood Institute, who is in throes of trying to win approval for the first gene transfer experiment in humans. Anderson's collaboration with Genetic Therapy served as a kind of first run through the process. In all, about 50 of these "Collaborative Research and Development Agreements," or CRADAS, have been signed by NIH scientists and their industrial partners. Dozens, or perhaps hundreds more, are in the works.

Whatever they may do for American competitiveness, these deals are causing confusion and anxiety on the Bethesda campus, even as researchers such as Anderson move ahead to forge their corporate alliances. Indeed, it was the agonizing memoranda and constant phone calls of Anderson to his overseers at NIH that were largely responsible for a recent retreat at NIH to discuss how best to handle the potential conflicts of interest that arise when corporations enter the picture at a government lab.* The session raised, however, as many questions as it answered.

By their very nature, the collaborations mandated by the technology transfer law violate long-standing policies at NIH concerning outside work and compensation. An even bigger concern is how NIH can manage its new corporate responsibilities without selling its soul.

The collaborative agreements go far beyond the consulting that many NIH scientists do for pharmaceutical and biotechnology companies. A consultant simply rents his brain. He does it on his own time. And he must take pains to discuss only what is in the public domain and what constitutes his own "general knowledge and expertise." It is in fact a crime to reveal tantalizing details of ongoing and unpublished experiments to a company without making those same details known to the rest of the world. For his help, a consultant may earn a total of $25,000 a year, a figure that was reached by only three researchers at NIH last year. The average moonlighter earned closer to $5000.

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A collaborator, though, is in a different realm. Unlike the consultant who does his work on the weekends, the collaborator is fulfilling his "official duties." He may enter into a close and lasting relationship with his corporate sponsor. As an example of how the relationship works, consider the arrangement between Anderson and his colleagues in Genetic Therapy. They work shoulder to shoulder at the bench. And unlike a consultant, Anderson shares with Genetic Therapy proprietary information, trade secrets, and the raw data of ongoing experiments. Indeed, that is the whole point of a true collaboration.

For its part, Genetic Therapy gets an exclusive right to license anything developed during the collaboration. The business, particularly those that are new and small like Genetic Therapy, also gets to bathe in the prestige of working with a gifted scientist from NIH, which cannot hurt when it comes time to raise more capital.

What the government scientist gets in return is resources—money for travel, postdocs, and equipment—and the smarts of his counterparts in the company. Most important for Anderson is the support for staff. Anderson says that four researchers in his lab were ready to leave NIH for jobs in academia or industry, but that the creation of Genetic Therapy kept them in town. The four now work for the company and continue to collaborate with Anderson.

Anderson is not allowed to serve on the board of directors of Genetic Therapy, though he says he does play a large role in shaping the company's scientific agenda. He may not, though, receive a salary for his contributions, nor can he own stock in the company. But he and other collaborators may be eligible to receive royalties of up to $100,000 a year.

In an age of budget deficits and flat funding for many labs at NIH, these partnerships can provide "invaluable resources," says Anderson, particularly when the company can truly advance the mission of the government lab.

There is palpable fear, though, that industrial partnerships may begin to insidiously undermine the mission of NIH. "This is not the time for NIH to deemphasize basic research and devote increasing resources to the development of marketable products," says John Eberhart, a senior adviser to the deputy director for intramural research at NIH. Eberhart wonders about the subtle effects of rubbing elbows with industry. "The danger is in excess, and in the power of money to affect how we think and what we do," he says.

Says Joseph Rall, deputy director for intramural research at NIH: "I'd rather see NIH scientists think about fundamental problems . . . rather than saying, 'I bet I could improve this technique and that some company could make a million dollars and I could make $10,000.' "

"We don't want to see NIH selling its soul to any company," says Philip Chen, associate director for intramural affairs at NIH. It is an unwritten rule at NIH, says Chen, that the collaborating company must provide true intellectual capital, not just cash.

There is the feeling, particularly among long-time veterans at NIH, that the new and

*Retreat on Conflict of Interest in Collaborations Between NIH/ADAMHA and Industry, 19 and 20 December 1988.

rapidly growing ties with business may alter the special environment of NIH, and cause once open and collegial scientists to dummy-up for fear of divulging the secrets of their industrial partners.

Most collaborative agreements between NIH and industry stipulate that the sponsoring company is allowed 30 days to review any papers that the NIH scientist wants to publish, with the idea being that the business can balk if the scientist reveals trade secrets in his methodology section.

There may be even more insidious impediments to open communication. For example, can NIH scientists who consult for a business communicate openly and freely with NIH scientists who collaborate with the same company? This question was the source of memo from Anderson to Chen in June, in which Anderson kept asking: "Who can talk to who without incurring a conflict of interest?"

Indeed, there are already inklings that this is occurring, says Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases. "In 21 years at NIH I have never gotten a blank stare before" when Fauci asked peers about reagents or enzymes. "Now I am beginning to get blank stares," says Fauci.

A short delay in publication, though, does not seem to be too burdensome, says Chen. In fact, many researchers delay publication for all kinds of reasons. Many are also hesitant to reveal the details of their work, regardless of whether or not a company is involved.

And about those blank stares? "Most researchers are more concerned about being scooped by their competitors than they're worried about withholding trade secrets," says Neil Reimers, director of technology licensing at Stanford University, who along with representatives from other universities and industry attended the retreat to voice their opinions on how to accomplish technology transfer without giving up the store. Reimers' conclusion on the current set-up at NIH? "Financially, right now it's almost too good a deal for the company."

Chen responds that there is a basic philosophical difference between Stanford and NIH. As their researchers get less and less from the government, universities are looking to industry for more support. But NIH looks at collaboration not as a funding mechanism, but as a way to fulfill the demands of Congress and the technology transfer act.

Still, the money does not hurt. But as the support from industry grows at NIH, Congress may see an opportunity to trim federal support. "It would be naïve to think otherwise," says Fauci. ■ **WILLIAM BOOTH**

NAE: Revamp Export Controls

Unless the U.S. government revises its policies on the export of computer equipment and software, U.S. industry will find it difficult to defend its markets and maintain its technological lead, says a new report by the National Academy of Engineering (NAE). The academy report calls for the government to recognize that other Western nations and developing countries are producing computer products that often are equivalent or superior to what domestic manufacturers sell.

American companies are likely to suffer if trade restrictions persist on commonplace components, personal computers, work stations, and software, says NAE in *Global Trends in Computer Technology and Their Impact on Export Control*. The report takes a broad look at the technological positions of Western nations and communist countries and highlights areas where safeguards on computer technologies are unnecessary and where trade controls are needed. The study stresses that maintaining the financial health of the nation's computer hardware and software companies is essential if the United States is going to promote continued innovation. This is a key factor behind the creative climate that has allowed American hardware and software vendors to maintain their edge in global markets, according to the report.

The United States should lift trade restrictions on computer equipment and software that have taken on a "commodity" status in world markets, says NAE's Committee To Study International Developments in Computer Science and Technology. Chaired by Seymour E. Goodman of the University of Arizona, the 17-member panel was critical of excessive trade restrictions on items such as personal computers. The group cited personal computers as the "epitome of the commodity computer product." They noted that trying to control the flow of these machines into Eastern Bloc countries is futile because they are manufactured worldwide.

The academy group says that government efforts to control the transfer of technology should focus on safeguarding supercomputer technology, advanced manufacturing methods for computer components, computer-automated design systems, and critical software. With respect to supercomputers, excessive regulation could handicap American manufacturers that are facing increasing competition from Japan. U.S. companies should not have to forfeit sales, the panel notes, because of bureaucratic delays in granting export licenses.

The growth of local and wide area computer networks that allow for rapid exchanges of data poses some potential problems, according to the academy report. The government should formulate ways to prevent "computer networks from becoming a channel for significant covert technology transfer. . . ." Federal officials, says the academy panel, must decide whether researchers from Eastern Bloc countries should be allowed to access commercial and university networks from within and outside of the United States. "Interestingly, it appears that some U.S. supercomputer centers may be accessible [by Eastern Bloc countries] through computer networks on a time-sharing basis . . . ," the panel observes.

One frontier where technology development needs to be protected is parallel processing, says the group. Advances in this computer architecture are expected to be made largely in the university and scientific communities—hence basic research results and ideas are expected to flow to Eastern Bloc countries.

While the United States should control exports of software to the Eastern Bloc, the academy panel says that trade to friendly nations should be as free as possible. American companies now dominate world software markets, but the committee notes that industrialized and developing nations are quickly making inroads. Needless restrictions on exports of software will only aid overseas software competitors, the report indicates. ■ **MARK CRAWFORD**

Samuel Broder New Head of NCI

It's official. President Ronald Reagan has named Samuel Broder, a 16-year veteran of the National Cancer Institute (NCI), to succeed Vincent T. DeVita, Jr., as NCI director. Rumors about Broder's impending appointment circulated in Washington for weeks before the White House announcement (*Science*, 2 December 1988, p. 1239).

Broder, 43, has been assistant director of NCI's clinical oncology program and is well known for his work with AZT, the drug that has shown some promise is treating people with AIDS. Broder is expected to place new emphasis on cancer prevention and diagnosis, while continuing DeVita's special interest in bringing therapy on-line as quickly as possible and making it widely available through NCI-supported cancer centers nationwide. ■ **BARBARA J. CULLITON**