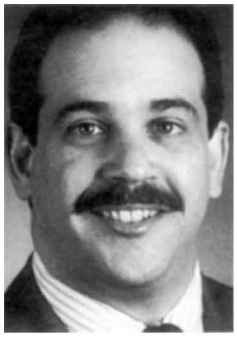
Transfer of technology is booming business as NIH asks companies to help themselves

Washington. A telephone call to the office of technology transfer (OTT) at the National Institutes of Health gives a clue to the changes going on inside. Whereas three years ago such a call would be answered by one of the office's three employees, it is now picked up by a voice-mail system worthy of a large corporation. Inquiries are electronically directed to one of four divisions with an overall staff approaching 50. Half a decade after Congress first allowed government agencies to commercialize their science, technology transfer has become big business at NIH.



Reid Adler

A long history of collaboration with pharmaceutical companies has allowed NIH to move into technology transfer more quickly than most other federally funded laboratories. Since its creation in 1987, the NIH office has broadened its responsibilities to cover technology transfer programmes at two other science agencies within the US Public Health Service (PHS) — the Alcohol, Drug Abuse and Mental Health Administration and the Centers for Disease Control.

Government technology transfer has its roots in the late 1970s, when Congress became interested in using the US patent system to promote the commercialization of inventions arising from federally funded research. In 1980 Congress changed the patent law to permit some such transfers. Then, in 1986, it broadened the legislation with the Federal Technology Transfer Act, which authorizes federally funded laboratories to enter into Cooperative Research and Development Agreements (CRADAs) with outside organizations, primarily industry, and to patent and licence their inventions.

Obtaining patent protection for government-made inventions lies at the heart of NIH's technology transfer activities and is strongly supported by Bernadine Healy, the director of NIH. It provides for public disclosure of inventions and protects the rights of institutes within NIH and of individual inventors, while stimulating interest in the commercialization of government-supported inventions by pharmaceutical and biotechnology companies. However, NIH created a furore last summer when it took the unprecedented step of filing patent applications on thousands of partial gene sequences (complementary DNA sequences) of unknown function.

Although CRADAs provide NIH scientists with additional resources, researchers from outside organizations are expected to make a significant intellectual contribution in jointly developing the technology. Government researchers may also receive a share of the royalties on any products licensed as a result of the collaboration.

Marc Schneebaum, vice-president and chief financial officer of Genetic Therapy Inc. (GTI), says that companies were unwilling before 1986 to collaborate with federally funded laboratories because "they couldn't protect their proprietary position". With the introduction of CRADAs, outside organizations can now secure exclusive licence agreements on any inventions that result from CRADAs. Although NIH researchers in a CRADA retain the right to publish their results, publication can be delayed to stake out a corporate claim to patent rights.

In the three and a half years since Reid Adler took up the post as director of OTT, the staff has grown in size from 2 to 42. But in the past six months, the number of CRADA applications has risen by 50 per cent to 7–10 submissions a month. Adler believes that the office needs to grow further, to at least 60 people, to handle the patenting, licensing and cooperative research programmes, to stay in touch with institutes within NIH and to keep industry abreast of possible collaborations.

Organizational changes are under way to simplify the technology transfer process. Since May, NIH's patent group, formerly part of the Office of the General Counsel is has joined OTT. Adler plans to establish joint patent and licensing teams to manage the portfolio of inventions and expand the services available to each institute. Although the number of patent application filings has remained level during the past three years, there are about 1,200 active patent applications at OTT. As the office files only 200 or so a year, half of the applications were filed before Adler arrived at NIH. The patent team plans to thin out the portfolio during the next six months and to be more selective in filing future patent applications.

What is in it for industry? For smaller companies, Adler says that CRADAs are a cost-effective way to increase the value of a company's research and development. For example, when HealthCare Investment Corporation started MedImmune Inc., it located it in Gaithersburg, Maryland, near the NIH campus, with the hope that the proximity would spur collaborations that could lead to new products. MedImmune now has seven CRADAs with NIH, five in immunotherapy and vaccine development. CRADAs have been "extremely useful to us", says James Young, vice-president for research and development at MedImmune, allowing "us to expand our resource base" to include the entire NIH intramural science programme.

For GTI, also located in Maryland, NIH and its 540-bed hospital serve as the company's 'clinical outlet'. The company was cofounded in 1986 by W. French Anderson, one of the pioneers of gene therapy and formerly of NIH's National Heart, Lung and Blood Institute (NHLBI). GTI signed its first CRADA with NIH in 1988 and now has five collaborations to test gene-therapy approaches to a wide range of diseases, including adenosine deaminase (ADA) deficiency, AIDS, blood disorders, cancer and cystic fibrosis. In 1990, GTI became the first company to receive a licence from NIH for technology developed under a CRADA carried out in conjunction with NHLBI and the National Cancer Institute.

But some other companies are still sceptical that government technology can be easily made into commercial products. Mark Furth, vice president of Regeneron Inc. in Tarrytown, New York, says that "dealing with the government is too slow to rely on" and that the company tries to "let science drive what we do" rather than promising to work with a government agency. Regeneron is developing compounds for the treatment of various neurological disorders such as Alzheimer's disease, amyotrophic lateral sclerosis (ALS) and Parkinson's disease. It has more than 100 collaborations with universities worldwide, but only one CRADA (with a protein structure group at NIH's National Institute of Diabetes and Digestive and Kidney Diseases).

Most discussions concerning CRADAs involve the scope of the research and what each party will contribute, but the issue of pricing is also being closely watched by industry. An existing clause allows NIH to exercise some control over the pricing of products developed through the programme, and industry feels that it is a disincentive to becoming involved in CRADAs.

For the past decade, federally funded laboratories have grappled with how to create, run and organize technology transfer programmes. What is needed in the 1990s, Adler says, is greater professionalism among technology transfer staff, a better allocation of resources and increased collaboration between agencies within PHS. He hopes that a new association of federal technology transfer executives (see *Nature* **358**, 362; 1992) will promote the sharing of ideas and information and eliminate the need to "reinvent the wheel" at every step of the technology transfer process. **Diane Gershon**