

TECHNOLOGY TRANSFER

NIH INVENTION DEVELOPMENT PROGRAM ADVANCES

WASHINGTON, D.C.—With some 5,000 researchers at its disposal, the National Institutes of Health (NIH, Bethesda, MD) churns out a great deal of biomedical know-how—much of it with commercial potential. To realize this potential more fully, NIH and other Public Health Service (PHS) agencies, particularly the Alcohol, Drug Abuse and Mental Health Administration (ADAMHA) are centralizing and streamlining their technology transfer programs. In business terms, slowly but surely the word is getting out that NIH and other PHS agencies are making reasonable deals.

Since 1986 when Congress approved the Federal Technology Transfer Act (FTTA), federal agencies self-consciously began seeking ways of making their research more accessible to the private sector. One way to do this is through cooperative research and development agreements (CRADA). Since NIH signed its first CRADA in late 1986, PHS has established nearly 100 such agreements (about 80 percent within NIH), with another 80 pending. The num-

ber could grow to an equilibrium level of between 400 and 600 over the next decade.

To encourage these developments, NIH has been streamlining procedures to minimize the bureaucratic hurdles facing prospective partners from the private sector. One product of these efforts—the industry-critiqued, revamped model CRADA agreement—is expected in its final form this October. PHS has also developed other documents outlining its policy positions on patent licensing

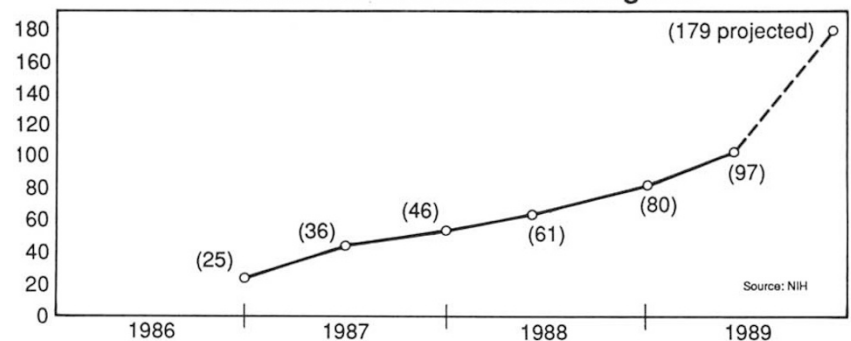
older, more established firms because the CRADAs are “a way for the small companies to substantially augment their research,” he notes. Because such agreements are part of a “two-way street...collaborations with industry also benefit research at NIH.”

Because of the natural lag between forming CRADAs and reaping actual gains, such as the patenting of inventions, the subsequent phase of negotiating patent licensing agreements over inventions arising from CRADAs is just beginning for NIH and

PUBLIC HEALTH SERVICE COOPERATIVE R&D AGREEMENTS

	Number signed	Cumulative total
1986 (includes pre-Fed. Techno. Transfer Act)	25	25
1987: (Jan.-June)	11	36
(July-Dec.)	10	46
1988: (Jan.-June)	15	61
(July-Dec.)	19	80
1989 (first 5 months)	17	97
1989 (currently in negotiation):	82	179 (projected)

Cumulative Number of CRADAs Signed:



and on fair pricing of commercial products—with considerable help and advice from the industrial and academic communities.

Most of these efforts now are coordinated through the NIH/ADAMHA Office of Invention Development (OID). Before the office began consolidating NIH technology transfer efforts, “each institute had its own approach, and companies dealing with them were not so happy,” says OID director Reid Adler. Often, there were simply too many “pieces of paper” for industry lawyers to shuffle, each with slightly different messages in the fine print. Thus, to all but the most determined corporate lawyers, access to NIH technology was blocked by a seemingly impenetrable bureaucratic jungle.

“Things have speeded up a lot since last year...[with] big and little companies interested” in what NIH has to offer, Adler says. Probably, more of the cooperative agreements now being reached involve smaller biotechnology companies instead of

some of its corporate partners. “No actual negotiations have taken place,” Adler says. “But we need to set royalty rates and benchmark performance standards for getting [pharmaceutical products] into the FDA approval process.” Separate from the CRADAs but parallel in some respects is a program enabling companies to license NIH technology directly. Some such agreements are already in place, with NIH investigators and their laboratories entitled to receive a share of any royalties.

NIH is actively seeking appropriate corporate research partners. “The more commercially oriented researchers at NIH have already signed” agreements, says Nina Siegler of OID. “We are now helping others to identify companies and to determine where their research may have commercial potential.” Toward that end, the office is sponsoring the “Second Annual NIH/ADAMHA Industry Collaboration Forum,” on October 3, 1989 in Bethesda, MD.

—Jeffrey L. Fox

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