Rocky Road for Federal Research Inc.

Congress sparked a revolution in technology transfer with laws that allow companies to work more closely with federal labs. So why is industry so unhappy?

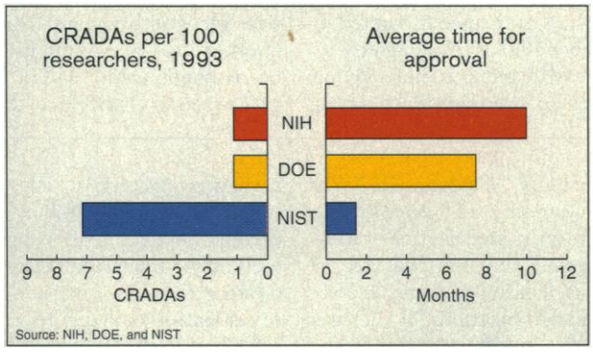
In a series of laws passed during the 1980s, Congress laid the foundation for a revolution in technology transfer. Lawmakers created a way for federal laboratories to work collaboratively with industry, with the aim of turning the government's multibillion-dollar research investment into commercial products. The mechanism for that transfer of technology was called a Cooperative Research and Development Agreement, or CRADA.

The agreements, between companies and federal agencies, require both parties to invest roughly equal amounts in collaborative research. In return, the company receives first rights to intellectual property developed as a result of the collaboration and the researcher gains access to industrial technology and resources. Hundreds of CRADAs have been signed since the process was created in the late 1980s, and the first products are already nearing the market place. But the road to commercialization has been rocky, and many potential collaborators are now backing away, discouraged by stifling bureaucracy, delays, concerns about access, and limits on pricing.

The National Institutes of Health (NIH) was one of the first agencies to take the plunge, but its early successes have been blunted by a drug-pricing clause in the NIH CRADA that has left the pharmaceutical industry in a panic and caused several major drug companies to foreswear new CRADAs. The Department of Energy (DOE) saw CRADAs as a way to develop a peace-time mission for its national laboratories, but the transition has been slowed by red tape and controversial funding restrictions. Corporate researchers complain that the National Aeronautics and Space Administration (NASA) is stuck in an earlier era, when spin-offs were the preferred mode of operation, and say the agency has yet to embrace true collaboration with industry. Only the National Institute of Standards and Technology (NIST), created to work with the private sector, appears to be doing what Congress intended.

CRADAs are popular with industry: in just 3 years, DOE has approved more than 500 CRADAs, and it now turns away dozens of proposals each month from companies eager to stake a claim on government research projects. Indeed, it is the vast potential of CRADAs that has made companies increasingly critical of the flaws in the system.

Business executives and lawyers have tried lobbying, legal pressure, and public excoriation in an attempt to coax a better fit with industry's needs. Some of it has succeeded: This summer DOE announced a series of planned reforms, and the Department of Commerce, which houses NIST, has convened an interagency task force to improve the CRADA process. But in many other instances, the pitfalls of the CRADA process have simply left companies sputtering about lost potential.



Time and talent. The prevalence of CRADAs, and the time it takes to sign them, varies greatly among federal agencies.

Richard Marczewski of General Motors has overseen the signing of the largest single collection of CRADAs in the nation, but he's no fan of the process. Although the company's 40 deals have given it exclusive access to millions of dollars' worth of federal research, mostly at DOE labs, Marczewski is still fuming at the contortions he had to go through to get them. "The CRADA process at DOE sucks," he begins, before launching into the first of his many horror stories from the front lines of the tech-transfer wars. His opponent has been, at various times, government bureaucrats, federal contractors, lawyers, and his competitors in the auto industry.

One battle he's just won was the "Clean Car" CRADA that President Clinton signed with executives from the Big Three U.S. automakers in a much-publicized Rose Garden ceremony last month (*Science*, 8 October, p. 172). Negotiations among the automakers began in January 1992 after DOE rejected GM's original proposal for a single-company CRADA. Once the bitter rivals agreed to work together, they approached DOE's national labs, prompting "a food fight over which of them was going to get in on this," says Marczewski. Eventually, he recounts, "it was down to five national labs, three cut-throat competitors, and one federal agency." Then the DOE contractors that manage the labs—AT&T, Martin Marietta, and the University of California—decided that they also needed to approve the deal. In the end, the CRADA required 15 separate agreements, one for each party. "It took 18 months," the exasperated GM official says. "It was a real bear."

Although the clean-car pact may have brought together an unusual combination of partners, it reflects many of the problems companies encounter when pursuing CRADAs with a large research agency. As interviews with dozens of industry and government officials reveal, the CRADA revolution has not been the bloodless affair portrayed in the self-congratulatory press releases from the various federal laboratories. Promising deals have fallen apart as scientists waited years for lawyers and bureaucrats to negotiate the terms of the research collaborations. Controversial clauses in the agreements that prohibit transferring technology to foreign manufacturing plants, absolve the government of product liability, and open the door to federal-regulated drug pricing have frightened off many other potential collaborators. And industry rivalries continue to threaten the process as companies complain that CRADA deals are effectively subsidizing their competitors with government funds.

A department under fire

DOE tends to attract most of the complaints, mostly because it has the largest number of researchers (about 27,000 scientists and engineers) and because it has been most aggressive in seeking collaborations. The impetus is the need for its four large national defense labs—Los Alamos, Lawrence Livermore, Sandia, and Oak Ridge—to find new roles in a post–cold war era. One unique feature of DOE's CRADAs is that they are funded from a special pot of money rather than out of normal research and development budgets, as is the case at other agencies. DOE argues that the additional funds give DOE scientists an incentive to pursue

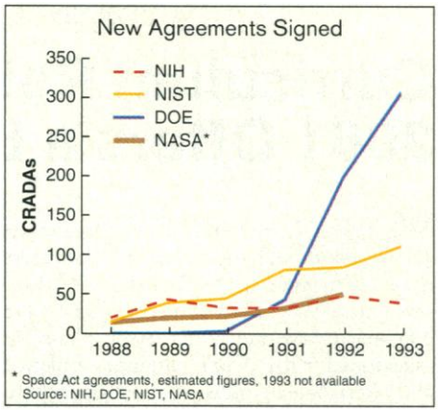
CRADAs. Unfortunately, the pot is so small —$200 million, or just over 3% of DOE's research and development budget—that last year the four largest DOE labs had to turn away nine of 10 proposals because of insufficient funding.

The separate budget also allows DOE to focus attention on the program. With 80% of DOE's CRADA money going to its defense labs, the congressional General Accounting Office (GAO) believes that a highly visible, separately funded CRADA program is part of a broader strategy by DOE "to justify continued support of the department's weapons laboratories." That emphasis on defense labs limits the participation of the rest of DOE's facilities. For example, a nondefense facility such as Brookhaven (New York) National Lab has signed only nine CRADAs, just 10% of Sandia's total.

Although some of DOE's problems with CRADAs are of its own making, others also apply to companies doing business with other agencies. One is a liability clause in the CRADA contract that requires the industrial partner to absolve the government of any risk should a product developed jointly cause harm. Marczewski offers a hypothetical example of why this kind of language keeps corporate lawyers up at night: "Let's say we invent a new kind of fuel injector. The government decides to [cross-license it to allow another manufacturer to] put it in a fighter plane. If the fighter blows up, we can be sued. We're liable for anything they might use the technology for." At least one industry group —the Computer Systems Policy Project (CSPP)—has managed to remove the liability language from its CRADAs.

A final concern is that CRADAs promote what used to be called "industrial policy"—the government's attempt to pick so-called winners and losers. This issue recently arose when several supercomputer manufacturers protested a $70 million agreement in which DOE labs, along with developing software for environmental and industrial uses, would help Cray Research Inc. to develop operating systems for its new computers. Cray's competitors said the CRADA amounted to a government subsidy of Cray's core business. Although DOE later removed operating systems from the scope of the CRADA, the general concern remains.

"A lot of these issues are lawsuits waiting to be filed," says Georgia Tech technology transfer expert David Roessner. "Some small company is going to go to court when a competitor strikes it rich as a result of a CRADA. They'll say they were working on the same thing and weren't informed—that they didn't have 'equal access' to the technology." As a result, DOE is moving toward industry-wide CRADAs. In March, for example, it announced a deal involving 10 DOE labs and five nonprofit textile research groups. At least a dozen other consortia, covering technologies from batteries to machine tools, now have CRADAs with DOE.



CRADA counting. The number of CRADAs at an agency can mask problems facing companies trying to make a deal.

NIH sputters

Other agencies have their own problems. NIH, which was one of the fastest out of the blocks (a 1989 *Science* article was titled "NIH, Inc.: The CRADA Boom"), last year signed fewer CRADAs than the year before. The reason? NIH officials and companies blame a "reasonable pricing" clause, unique to NIH CRADAs. The clause has its roots in the controversy over the pricing of the AIDS drug AZT, which was developed by Burroughs-Wellcome with NIH's help. Seeking to avoid another incident in which it was powerless to affect pricing despite having collaborated on a drug, NIH's parent agency, the Public Health Service, voluntarily inserted a fair-pricing provision in the NIH CRADA. Although it is essentially unenforceable as written, several members of Congress have focused on it as a potential way to compel drug companies to reveal what might otherwise be proprietary data on cost and pricing. The goal is to lower the price of drugs developed under an NIH CRADA.

"The whole issue of industry cooperation with government is being subsumed by price controls," says Max Hensley, a biotech intellectual property rights attorney. "People are asking, 'If I do a deal with government, is it an invitation to Capitol Hill' [to get involved]?' " As a result, many pharmaceutical and biotech companies are reconsidering CRADAs, and NIH officials say four of the largest—Pfizer, Abbott Laboratories, Merck and The Upjohn Co.—have told NIH that they plan to forego new CRADAs unless the pricing clause is removed. "We're concerned about the value of investing in something when we don't know what we're going to get out of it," says Godfrey Grant of Upjohn, which has not signed a new CRADA in more than a year.

Not all companies can afford to walk away from CRADAs, however. James Young, vice president for research and development at MedImmune Inc., a Maryland biotech startup, says that "we're smaller, and we need to get products to market." The company was able to delete the drug-pricing clause from some of its early CRADAs, he adds, but that was before the issue became so politically sensitive.

Other companies complain about delays in getting CRADAs approved by NIH. "The intent of CRADAs is a great idea," says Fran Heller of Celtrix Pharmaceutical Inc., a Santa Clara, California, biotech company. "But the execution leaves a lot to be desired. We have three CRADAs, but we'd probably have a lot more if it didn't take so long to execute." Processing time varies between NIH institutes, but a year is common at such large research centers as the National Cancer Institute. "When you've got a bunch of [industry and government] scientists eager to work together, to have to wait months for CRADA approval tends to put a damper on the party," says Michael Rogawski, an NIH neuroscientist who has two CRADAs and several false starts. Reid Adler, head of NIH's technology transfer office, says the agency is trying to streamline the review process by giving greater signing authority to the individual NIH institutes.

NASA: Lost in space?

The National Aeronautics and Space Administration (NASA) is not covered by the technology transfer laws that permit CRADAs. Instead, its collaborative research agreements come under the 1958 Space Act, and are known as Space Act Agreements.

NASA is considered by many in industry to be one of the least receptive agencies for collaborative research, in large part because of a tradition of developing technologies in relative isolation and then "spinning them off" to industry rather than involving industry from the outset. Says Roessner: "NASA's been living under the Space Act for 35 years—its whole notion is to find someone who will take an off-the-shelf technology. They don't feel the same sense of urgency as the DOE weapons labs do to collaborate with industry."

One scientist who recently left NASA's Goddard Space Flight Center in suburban Maryland recalls setting aside 10% of his budget several years ago for work with industry. NASA budget officials deleted the set-aside, however, telling him that "it wasn't essential." Today, Goddard, with 2000 scientists and engineers, has only two Space Act agreements.

NASA policy coordinator Tyrone Taylor agrees that NASA's culture doesn't encourage collaborative research, adding that "we're struggling to change that." Last year,

NASA examined its tech-transfer programs and concluded that "all too often, NASA employees, managers, contractors, and grantees don't consider tech transfer to be part of their jobs." But that attitude may be changing: Earlier this year, NASA Administrator Daniel Goldin sent a memo to all employees extolling the importance of tech transfer in the agency's mission, and a call to reform the agency's attitude even showed up in last month's report by Vice President Al Gore on reinventing government.

NIST finds the key

Among the top research agencies, only NIST appears to have managed to embrace CRADAs without getting smothered. Its budget is just one-fifth of the $1 billion that NIH spends on in-house research, but it supports more than twice as many active CRADAs. Industry officials attribute this mostly to NIST's mission—its researchers have traditionally been focused on industrial research issues, and their work tends to be among the most applied in the government. In contrast, "the bulk of NIH research is very fundamental and not of immediate commercial interest," explains NIH's Adler. Although NIST, like the other agencies, still has few products on the market to show for its CRADAs, it is gaining a reputation for exemplary technology transfer, a performance that has helped it to win a promise from President Clinton to more than triple its budget over the next 4 years. Companies attribute NIST's success to a compact bureaucracy, healthy funding, a culture of applied research, and a long history of industrial collaborations that could easily be converted to CRADAs.

Congress initiated the CRADA process and it is now starting to respond to the swelling chorus of complaints. Senators Jay Rockefeller (D–WV) and Dennis DeConcini (D–AZ) have just introduced a bill intended to reduce much of the delay in negotiating CRADAs by giving the industrial partner automatic ownership of any technology developed, with the government retaining only a paid-up license for its own use. In return, the corporate partner would either reimburse the federal lab for its research costs, or pay the equivalent of royalties, with the first $10,000 going to the government scientists themselves. Rockefeller will hold a hearing on the bill next week, where it is expected to be endorsed by the Clinton Administration. If so, the bill is expected to be folded into related legislation now on a congressional fast track, and could become law before the end of the year. As other legislators consider additional reforms of everything from DOE's budgeting to NASA's bureaucracy, it seems that industry's CRADA complaints may finally be having their intended effect.

–Christopher Anderson

Curriculum Reform: Project 2061 Offers a Benchmark

What should children learn about science, and when should they learn it? Educators have been grappling with those questions since the 1980s, when report after report concluded that traditional lesson plans are overstuffed with detail, alienate students, and often create confusion about the nature of science. On the basis of those findings, teachers and scientists alike decided science education needed a drastic overhaul.

As a result, reformers in all 50 states have been busy designing new ways to teach science, with several independent national projects and dozens of state efforts progressing simultaneously. The latest product is from Project 2061, sponsored by the American Association for the Advancement of Science (publisher of *Science*). On 29 October, the project is slated to release a major report called *Benchmarks for Scientific Literacy*, which offers detailed recommendations for the concepts students in each grade from K through 12 need to know. "It's a step toward recasting how we all think about the nature of science literacy. It promotes the notion that all children can understand how science operates, and how it connects to real life," says F. James Rutherford, who directs the project.

The recommendations of Project 2061 share common ground with those from the other major players in the science education reform, including the National Science Teachers Association (NSTA) and the National Research Council (NRC), as well as a chorus of states now redoing their science frameworks. Most of these efforts advocate fewer facts, more concepts, and giving students concrete, hands-on experiences (*Science*, 7 December 1990, p. 1327). Drafts of each reform are constantly circulating throughout the community, so that "We're all part of the same conversation," says Elizabeth Stage, who has just left the NRC's education project to co-direct a new multi-state effort on new ways of testing students, called the New Standards Project.

But not everything is sweet harmony in this field. There are key points of difference among the players, such as whether science lessons should be taught in a truly interdisciplinary fashion, and when to introduce certain tough concepts. The NRC, which is part of the National Academy of Sciences, is charged with identifying some order in the babel of reforms and creating national standards in curriculum, teaching, and assessment; a first draft is due early next year. But the academy is relatively new to K through 12 education, and some grumble that the independent projects should take the lead. "We've been doing this for 8 years," says Andrew

NATIONAL REFORM EFFORTS

Project & Year	Sponsor	Goal	Products
Standards for School Mathematics 1986	National Council of Teachers of Mathematics	National standards in math curricula, teaching and testing, K-12	Curriculum and Evaluation Standards, 1989; Professional Standards 1991
National Science Education Standards 1991	National Research Council	National standards in natural science curricula, teaching, and assessment, K-12	Draft samplers circulating; complete draft due in early1994
New Standards Project 1991	Learning, Research and Development Center; Natl. Center on Education and the Economy	New ways to assess students' science achievement K-12	Science exams to be available in 1995-96.
Project 2061 1985	Amer. Assoc. for the Advancement of Science	Comprehensive, systemic reform K-12, including curricula goals in natural, social sciences, math and technology	Science for All Americans, 1989 rev.1993; *Benchmarks* for Science Literacy 1993.
Scope, Sequence and Coordination 1989	Natl. Science Teachers Assoc.	Revised curriculum, sequence of instruction in natural sciences, grades 6-12	Content Core revised ed. 1993