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Cooperative Research and Development Agreements (CRADAs)

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Summary

A Cooperative Research and Development Agreement (CRADA) is a mechanism established by P.L.99-502, the Federal Technology Transfer Act, to allow the transfer of technology, knowledge, and expertise from government laboratories to the private sector for further development and commercialization. It also provides a means for federal scientists and engineers to obtain state-of-the-art technical information from the industrial community. The work done under a CRADA must not detract from the mission responsibilities of the laboratory. The government provides support in the way of overhead for research and development (R&D) performed in the federal laboratory and is prohibited from providing direct funding to the partner in the collaborative effort. Currently, over 5,000 CRADAs have been signed (including NASA Space Act Agreements). As the 106th Congress begins the debate over its approach to science and technology, the role of CRADAs is expected to be discussed within the context of federal support for R&D.

Rationale

In pursuit of mission requirements, federal departments and agencies spend approximately $76 billion per year on research and development; almost a third of this to support R&D performed in the government laboratory system. Such an effort has resulted in new and improved technologies and manufacturing techniques that may provide additional benefits beyond specific mission-related use. For example, while the major portion of total federal R&D spending has been in the defense arena, government-financed work has led or contributed to new commercial products and processes including, but not limited to, antibiotics, plastics, jet aircraft, computers, electronics, and genetically engineered drugs (e.g., insulin and human growth hormone). Technology transfer is one way, proponents argue, that federally funded R&D can be further developed and applied by the private sector to meet other national needs associated with economic growth. The increasing competitive pressures on U.S. firms in the international marketplace, coupled with the government's requirements for goods and services, can make the collaboration between federal laboratories and industry through technology

transfer beneficial to both sectors. Although opponents may argue that these activities detract from budgeted research, the knowledge base created by agency-supported R&D may serve as a foundation for additional commercially relevant efforts in companies while the government research enterprise is advanced through interaction with innovative firms. This transfer is facilitated by cooperative research and development agreements (CRADAs), a particular legal instrument created by the Federal Technology Transfer Act of 1986 (P.L.99-502).

The Federal Interest[1]

The movement of technology from the federal laboratories to industry is achieved through technology transfer, a process by which technology developed in one organization, in one area, or for one purpose is applied in another organization, in another area, or for another purpose. Technology transfer can have different meanings in different situations. In some instances, it refers to the transfer of legal rights, such as the assignment of patent title to a contractor or the licensing of a government-owned patent to a private firm. In other cases, the transfer endeavor involves the informal movement of "know-how" (information, knowledge, and skills) through person-to-person interaction. A successful transfer is in the actual use of the product or process. Without this, the benefits from more efficient and effective provision of goods and services are not achieved.

The federal interest in the transfer of technology is based on several factors. With the rapid pace of technological advancement in industry, the expertise, skills, products, and processes necessary for the agencies to meet their mission requirements often is only available in the private sector. Thus, cooperative activities with industrial scientists and engineers can be critical to the laboratory's successful completion of its research agenda. The government also requires certain goods and services to operate. Much of the research it funds is directed at developing the knowledge and expertise necessary to formulate these products and processes. However, because the government has neither the mandate nor the capability to commercialize the results of the federal R&D effort, it must purchase technologies necessary to meet mission requirements from the private sector. Technology transfer is a mechanism to get federally generated technology and technical know-how to the business community where it can be developed, commercialized, and made available for use and adaptation in the public sector.

Federal involvement in technology transfer also arises from an interest in promoting the economic growth that is vital to the Nation's welfare and security. It is through further development, refinement, and marketing that the results of research become diffused throughout the economy and can generate growth. Economic benefits of a technology or technique accrue when a product, process, or service is brought to the marketplace where it can be sold or used to increase quality and productivity. When technology transfer is successful, new and different products or processes become available to meet or induce market demand. Transfer from the federal laboratories also can result in substantial increases in employment and income generated at the firm level.

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[1]For a detailed discussion of the technology transfer issue see: Congressional Research Service, *Technology Transfer: Use of Federally Funded Research and Development*, by Wendy H. Schacht, CRS Issue Brief 85031.

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In addition, it may be a way to assist companies that have been dependent on defense contracts and procurement to convert to manufacturing for the civilian marketplace.

In the past, despite the potential offered by the resources of the government laboratory system, the commercialization level of the results of federally funded research and development remained low. There were various reasons for this, one of which is the fact that many technologies and patents have no commercial application or have little value in the marketplace. Because federal laboratory R&D is generally undertaken to meet an agency's mission or because there are insufficient incentives for private sector investment in research that the government deems in the national interest, decisions regarding laboratory priorities reflect public sector, rather than commercial needs. Thus, transfer often depended on attempts to ascertain new commercial applications of technologies developed for government use rather than on the development of technologies in response to market demand.

Additional barriers to transfer involve costs. It has been estimated that research accounts for approximately 25% of expenditures associated with bringing a new product or process to market. Thus, while it might be advantageous for companies to rely on government funded research, there are still significant added investments necessary to achieve commercialization after the transfer has occurred. However, industry unfamiliarity with these technologies, the "not invented here" syndrome, and ambiguities associated with obtaining title to or exclusive license for federally owned patents also serve to limit technology transfer.

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The Legislative Foundation

The legislative basis for technology transfer is P.L. 96-480, the Stevenson-Wydler Technology Innovation Act of 1980, as amended. This law explicitly states that "It is the continuing responsibility of the Federal Government to ensure the full use of the results of the Nation's Federal investment in research and development." Technology transfer was mandated as an expressed part of each agency's mission. Various institutional mechanisms were created by which federal departments and their laboratories could accomplish such efforts.

The initial response to new opportunities for use of federal laboratory resources was less than expected on behalf of both the private and the public sectors. As a consequence, additional incentives were considered by the Congress resulting in enactment of P.L. 99-502, the Federal Technology Transfer Act of 1986. This law established a new tool, the "cooperative research and development agreement," to be used for joint work between federal laboratories and the business community. First limited to government-owned, government-operated laboratories (GOGOs), the authority to enter into CRADAs was extended to government-owned, contractor-operated laboratories (GOCOs), generally the laboratories of the Department of Energy (DOE), by the FY1990 Defense Authorization Act, P.L. 101-189. In the 104th Congress, the Technology Transfer Improvements and Advancement Act (P.L. 104-113), provided additional guidelines to simplify the negotiation of CRADAs and to reduce any private sector uncertainty in working with the government.

CRADAs Defined

A CRADA is a specific legal document (**not** a procurement contract) which defines the collaborative venture. It is intended to be developed at the laboratory level, with limited agency review. In agencies which operate their own laboratories, the laboratory director is permitted to make decisions to participate in CRADAs in an effort to decentralize and expedite the technology transfer process. However, at agencies which use contractors to run their laboratories, specifically the Department of Energy, the CRADA has to be approved by headquarters.

The work performed under a cooperative research and development agreement must be consistent with the laboratory's mission. In pursuing these joint efforts, the laboratory may accept funds, personnel, services, and property from the collaborating party and may provide personnel, services, and property to the participating organization. The government can cover overhead costs incurred in support of the CRADA, but is expressly **prohibited** from providing **direct** funding to the industrial partner. In GOGO laboratories, this support comes directly from budgeted R&D accounts. The Energy Department generally relied on a competitive selection process run by headquarters which allocated funding specifically designated to cover the federal portion of the CRADA. However, the FY1994 appropriations eliminated the line item for technology transfer in the non-defense laboratories, instructing that such efforts be part of on-going programmatic activities. The line item still exists in the DOE defense laboratories' budgets, although at a significantly decreased level of funding.

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The legislation does not specify the dispensation of patents derived from the collaborative work, allowing the agencies to develop their own policies. However, under a CRADA, title to, or licenses for, inventions made by a laboratory employee may be granted in advance to the participating company by the director of the laboratory. The director may also negotiate licensing agreements for related government-owned inventions previously made at that laboratory to facilitate cooperative ventures. In addition, he can waive, in advance, any right of ownership the government might have on inventions resulting from the joint effort regardless of size of the collaborating company. This latter provision diverges from other patent law which requires that title to inventions made under federal R&D funding be given only to small businesses, not-for-profits, and universities. In all cases, the government retains a nonexclusive, nontransferable, irrevocable, paid-up license "to practice, or have practiced," the invention for its own needs.[2]

Laboratory personnel and former employees are permitted to participate in commercialization activities if these are consistent with the agencies' regulations and rules of conduct. Federal employees are subject to conflict of interest restraints. In the case of government-owned, contractor-operated laboratories, P.L. 101-189 required that conflict of interest provisions regarding CRADAs be included in the operating contracts within 150 days of enactment of the law. Preference for CRADAs is given to small businesses, companies which will manufacture in the United States, or foreign firms from

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[2]For additional information see: Congressional Research Service, *The Bayh-Dole Act: Patent Policy and the Commercialization of Technology,* by Wendy H. Schacht, CRS Report 94-501, 1994.

countries that permit American companies to enter into similar arrangements. According to the Senate report (S.Rept. 99-283), which accompanied the legislation, "the authorities conveyed by [the section dealing with CRADAs] are permissive" to promote the widest use of this arrangement. To date, over 5,000 cooperative research and development agreements have been signed across all federal departments and agencies (including NASA Space Act Agreements which are *similar*, but mandated by different legislation).

It should be noted here that CRADAs are only one form of cooperative activity, but because they can be easily identified and quantified they tend to be the most visible. Other mechanisms include personnel exchanges and visits; licensing of patents; work for others; educational initiatives; information dissemination; the use of special laboratory facilities and centers set up in particular technological areas; cooperative assistance to state and local programs; and the spinoff of new firms. Currently, federal laboratories legislatively are prohibited from competing with the private sector and can only offer the use of expertise and equipment which is not readily available elsewhere. Technology transfer and cooperative efforts are expressly forbidden to interfer with the laboratories' R&D mission-related activities.

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Observations and Issues

Over the past 15 years, the Congress has enacted various laws designed to facilitate cooperative R&D between and among government, industry, and academia. These laws include (but are not limited to) tax credits for industrial payments to universities for the performance of R&D, changes in the antitrust laws as they pertain to cooperative research and joint manufacturing, and improved technology transfer from federal laboratories to the private sector.[3] The intent behind these legislative initiatives is to encourage collaborative ventures and thereby reduce the risks and costs associated with R&D as well as permit work to be undertaken that crosses traditional boundaries of expertise and experience leading to the development of new technologies and manufacturing processes for the marketplace.

There has not been an independent, cross-agency evaluation of CRADAs, in part because of the inherent time lag between research and commercialization and in part because of an absence of standardized departmental measures of success. The General Accounting Office (GAO) reviewed 10 CRADAs among a group selected by agencies as having achieved their goals. In this December 1994 study,[4] GAO found that the benefits of collaboration include new commercial products, advancements in R&D programs, and assistance in meeting agency mission requirements. Noting that the CRADAs studies were not necessarily representative of all such efforts, the report concluded that CRADAs can be a "valuable asset" and "... government-industry collaboration can have a positive impact on certain economic, health, and environmental needs of the United States."

In both the 104th Congress and the 105th Congress there were indications that a majority of Members favored refocusing federal funding to support basic research rather

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[3]For additional discussion see: Congressional Research Service, *Cooperative R&D: Federal Efforts to Promote Industrial Competitiveness*, Wendy H. Schacht, CRS Issue Brief 89056.

[4]General Accounting Office, *Technology Transfers: Benefits of Cooperative R&D Agreements*, Washington, D.C., 1994, RCED-95-52, December 1994.

than technology development. Indirect measures to encourage technological advancement in the private sector (e.g., tax incentives) appeared to be preferable to direct federal spending. CRADAs, in particular, are a means to take government funded basic research from the federal laboratory system and move it to the industrial community for commercialization to meet both agency mission requirements and other national needs associated with the economic growth which comes from new products and processes. It should also be recognized that the government is expressly prohibited from providing direct financial support to partners in the cooperative venture under a CRADA. Therefore, this approach may meet the criteria expressed as acceptable to the Congress.

As the new Congress determines its approach to science and technology, the role of CRADAs is expected to be debated. The recent increase in the number of cooperative research and development agreements and the expanded industry interest in this activity implies that both the public and private sectors see value in this activity. The fact that companies must invest time and money in technology transfer projects helps to insure that the R&D is relevant to industry needs. Support for CRADAs from departmental R&D budgets is designed to guarantee that the work is consistent with the missions of the federal agencies.

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However, the successful implementation of the technology transfer mandate has raised issues related to specific CRADA arrangements and thus led to additional questions.[5] Is the technology transfer mandate in conflict with other governmental objectives such as economic security? Because industries and companies are interdependent, can the technology transfer interests of U.S. firms that have a technological lead be balanced with those that do not? How does the government balance the interest of one industry or one company with another? How can the government's interests be balanced with those of industry? Does the current system allow both the laboratories (thus, the American public) and the private sector to achieve commensurate benefits? The way in which these issue are resolved and the manner in which specific circumstances are addressed may influence whether or not CRADAs continue to be a viable mechanism to transfer technology from the federal government to the private sector and from industry to the federal laboratories.

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[5]For additional discussion see: Congressional Research Service, *R&D Partnerships and Intellectual Property: Implications for U.S. Policy*, by Wendy H. Schacht, CRS Report 98-862 and Congressional Research Service, *Cooperative Research and Development Agreements and Semiconductor Technology: Issues Involving the "DOE-Intel CRADA,"* by Wendy H. Schacht and Glenn J. McLoughlin, CRS Report 98-81.