TECH TRANSFER 2000:

MAKING PARTNERSHIPS WORK

Office of Technology Policy
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FOREWORD

The manner in which the federal government works with the private sector in developing and diffusing technologies changed in fundamental ways with passage of the Bayh-Dole, Stevenson-Wydler, and Federal Technology Transfer Acts in the 1980s. The agencies and the private sector began to find ways to partner in the development of technologies that both furthered agency missions and advanced the competitiveness of industry and the strength of our economy. Many successful partnerships have been built and many technologies that had their inception in the federal laboratories have now become important parts of the commercial technology base.

The Office of Technology Policy is pleased to provide this review of agency and private sector activities under these laws, pursuant to the Stevenson-Wydler Act. In this report, we take a careful look at the ways in which the Cooperative Research and Development Agreement (CRADA) authority and the patent licensing authority are being used by the agencies. The breadth and complexity of the federal research establishment and the wide variety of partnerships formed with the private sector make it difficult to provide a simple overview of the federal technology transfer system. Indeed, that is one of the major insights to be gained from the report—that the generic procedures for partnering and licensing provided by the federal laws have taken on different shapes as they have been integrated into the distinctive research missions of the agencies.

Subject to this important caveat, we have tried to present a comprehensive look at the principal issues currently being addressed by agencies and their private sector partners. The data presented in Appendix C concerning agency activities under the technology transfer laws is for Fiscal Year 1998. In order to provide some comparability, the data concerning research budgets for the agencies discussed in Appendix A is also for Fiscal Year 1998. Data for subsequent years will be presented in later published reports and at our website, www.ta.doc.gov. Some of the challenges identified have faced the programs since the start. Others are new and, in many cases, the fruits of broader use of the programs. As a part of our review, we have suggested goals we believe the agencies and their partners should strive for in order to meet these challenges. We will continue to work with the agencies and industry to ensure that these important tools are used to accomplish the overriding goal of a strong and competitive economy.

Kelly H. Carnes, Assistant Secretary for Technology Policy

Acknowledgments

The Office of Technology Policy was fortunate to have the assistance of Gilbert (Gib) Marguth, of Sandia National Laboratory, in creating this report. His knowledge of technology transfer and his insights into the operation of the federal programs were invaluable in identifying the issues to be addressed and putting the report together. The report also benefited from the involvement of representatives of the technology transfer organizations of the principal research-performing departments and agencies (who are also participants in the Interagency Working Group on Technology Transfer). Finally, discussions with the Industrial Research Institute's External Research Directors' Network and research work performed by Drs. David Roessner and Robert Carr of the Stanford Research Institute helped to identify concerns of the laboratories' private sector partners.

Chapter 1: Executive Summary

CRADAs and patent licensing, the technology transfer tools discussed in this report, provide relatively simple ways for U.S. businesses to develop federally funded innovations into commercially useful products and processes. These tools were adopted at a time of unprecedented technological challenge to U.S. industry but are useful even in today's dynamic technology markets.

Our review shows that CRADAs and patent licensing have been broadly accepted by industry and the laboratories as a means of partnering in technology transfer. Difficult issues remain to be addressed, many of which are similar to those raised in our 1996 *Effective Partnering* report. The principal challenge is for the agencies to develop, with their industry partners and others, a set of measures for these activities-measures that are based on a shared vision of the outcomes they can achieve.

Integrating Competitiveness Goals with Agency Missions

One of the principal lessons from our review is that CRADAs and patent licensing have evolved in different ways within each agency—ways that serve that agency's mission as well as provide innovations of value to the private sector. Where the agency mission aligns with the commercial objectives of an industry sector, the potential for partnerships is particularly strong. In those circumstances, the tools not only benefit the industry and the economy, but also help accomplish the mission of the agency.

The National Institutes of Health and the Agricultural Research Service are two agencies whose missions are often accomplished through the activities of specific industry sectors and whose technology transfer activities have been particularly fruitful, both in producing new commercial products and services and in achieving their agency goals. Other agencies, like the Departments of Defense and Energy, receive mission benefit from the tools in a different way. They work with many different industry sectors interested in their broad-ranging research as a source of innovations with commercial significance. These cooperative activities also help discharge their missions—either by providing needed products and services or building technical proficiency in a mission-related field.

It is particularly important to recognize these differences among the agencies in assessing the results of CRADAs and patent licensing. In addition to the benefits to industry and the economy generally contem-

plated at the time of enactment, these tools have also helped the agencies achieve mission objectives.

More Help Needed in Finding the Right Laboratory

Many of the challenges currently facing laboratory partnerships with the private sector have been present from the start. Identifying the federal laboratories with expertise in a particular field was an extremely difficult challenge at the beginning of these programs. While the efforts of the Federal Laboratory Consortium and the individual agencies have lessened the challenge, more needs to be done, especially for businesses new to the federal laboratory system.

Managing Intellectual Property Must Become an Agency Priority

The management of intellectual property will always be an area of tension, given the differing perspectives of the agencies and their corporate partners. As both sides have gained experience in such partnerships, however, the issues have been refined and are more limited and specific. The procedures applicable to exclusive licensing, including the notice and comment procedure, have sometimes caused strain between the agencies and their partners. Similarly, the application of the concept of "subject inventions" under CRADAs to pre-existing inventions has sometimes led to misunderstandings concerning the treatment of intellectual property. Although the CRADA law's provisions for the confidential treatment of CRADA data have been used by some agencies to protect information needed by CRADA partners, there are limits to the scope of protection that can be provided in this way. Finally, even though agencies generally seek licenses in the inventions of their CRADA partners, private sector partners are not clear why such licenses are needed. Since the agencies have been given discretion to forego such licenses, this subject deserves further exploration.

CRADAs Can Be Used Effectively in Many Different Circumstances

CRADAs are extremely flexible instruments. While their use in certain circumstances has been challenged (e.g., where used as a substitute for a contract subject to the procurement regulations), they are legitimately used in an extremely broad range of circumstances (differing principally

in the degree to which proprietary considerations are involved in the research). Agencies need to be sensitive to these different types of cooperative research agreements and flexible in prescribing terms and conditions appropriate to each type. Several types of CRADAs particularly useful for work in support of local and regional technology-based economic development initiatives have been developed, and the agencies' "model" agreements of these types should be made more broadly available.

Domestic Manufacture Requirements Pose Problems for Global Companies

The most serious industry/government issues discussed relate to US competitiveness concerns embodied in CRADA and licensing law. The most difficult issues involve the requirement of substantial domestic manufacture of any products resulting from the CRADA or licensed technology. Industry concerns center on the difficulty, if not impossibility, of predicting the place of manufacture of possible future products at the time of entering into a cooperative agreement to perform research that may ultimately lead to such products. Finally, the treatment of liability and indemnification issues in CRADA agreements has been troublesome to industry because of the severity of the contractual clauses generally proposed by the agencies and their apparent inflexibility in considering alternatives.

CRADAs Have Not Been as Effective with State and Local Governments and Universities as Other Cooperative Arrangements

Research partnerships among the laboratories and both state and local governments and universities have generally proven less popular than anticipated at the time of passage of the CRADA legislation. The treatment of intellectual property has sometimes been an obstacle to CRADAs with universities, although some agencies have been able to manage this issue. Partnerships with state and local governments have been successful in supporting economic development but CRADAs have not been generally effective as a tool for helping those governments meet their own technology needs. Using CRADAs for this purpose may require some changes in policies and practice both at the laboratories and among the state and local governments.

Measures of Success in Technology Transfer Must Be Developed by Agencies in Partnership with the Business Community

Agencies need to consider, with their business partners, the direction they want to take with CRADA and patent licensing procedures. We have suggested four goals that the agencies should pursue, in partnership with their business partners, to further improve their effectiveness:

- First, the laboratories need to manage their intellectual resources to ensure that maximum value is derived both for their agency mission and for the economy as a whole. This will require regular reviews of the advances produced by their work and an assessment of the appropriate treatment of these advances (i.e., publication, patent protection, or holding for further development).

- A second goal is to make it easier for others (principally in the private sector) to identify the capabilities of the laboratories to solve specific problems.

- Third, the agencies and their laboratories need to develop a process, in partnership with the private sector, and others, to identify and address barriers to collaboration on a continuing basis.

- Finally, we suggest that the federal government must develop the measures needed to monitor the technology transfer process and must have a system in place to collect and disseminate such information.

Chapter 2: Agency Implementation of Technology Transfer Authorities

To understand the issues discussed in later sections of the report, it is important to first consider the ways in which the agencies have integrated their technology transfer authorities with their missions. First, these new authorities required the agencies to consider how the goal of furthering technological competitiveness squared with their traditional missions, such as improving the public health or maintaining our national defense. Second, the agencies had to make decisions concerning these new kinds of agreements at a pace that was satisfactory to their private sector partners, without compromising consistency of agency decision-making or ignoring the substantive requirements imposed on them to further domestic competitiveness (and not simply strengthen an individual company).

Commercialization Objectives and Agency Missions

The integration of these new private-sector-focused mechanisms into agency missions has been a particularly complex process. All of the agencies seek to disseminate the results of their research to the scientific and technical community, to industry, and often to the general public through publications, personnel exchanges, conferences, and many other means. The manner in which the CRADA and licensing mechanisms are integrated into the agency depends in large part on how the commercialization process meshes with the agency's mission, and its preexisting technology dissemination mechanisms.

For some agencies, the development of new commercial products and services from their research can play an important part in furthering their mission. The National Institutes of Health, for example, recognize the need for commercial development of portions of their research in order to produce new medicines that will improve the public health. In other circumstances, the development of the commercial products from agency research may not contribute directly to the agency mission but may further the agency's goals by creating a level of expertise in the research area that can be drawn on for mission purposes. The Department of Defense (DoD) encourages technology transfer in the case of technologies with both defense and commercial applications, viewing such efforts as a way of controlling costs of developing defense uses for new technologies. Finally, there is a third situation, in which mission-related research leads to a result with commercial applications that have little direct relevance

Technology transfer not only provides important new technologies for private sector use but also furthers the missions of the agencies.

to the mission of the agency but that may produce new products with significant commercial potential.

As this brief review suggests, technology transfer, as practiced by the agencies, is an activity that not only provides improrant new technologies for private sector use but also furthers the missions of the agencies.

Expedited Decision-making, Consistency, and Compliance with Decisional Standards

The Stevenson-Wydler Act sought to speed the agency decision process with respect to CRADAs by encouraging decentralization of the authority to enter such agreements. At the same time, the agencies wished to achieve consistency in their decision-making and to observe the standards that Congress had imposed on the use of the CRADA mechanism. The manner in which the agencies balance these competing objectives is affected by their organizational structure and by the size and complexity of their laboratory systems, producing different technology transfer systems at different agencies. The adjusting of that balance is a continuing process, responsive to the experiences of the agencies and the suggestions of their business partners.

This report is itself a result of interagency cooperation in the identification and analysis of some common issues.

The agencies have also worked together to address implementation issues on an interagency basis through the Interagency Working Group on Technology Transfer and the Federal Laboratory Consortium (FLC). The Working Group was initiated and chaired by the Department of Commerce, following passage of the Federal Technology Transfer Act in 1986. It provides a means of sharing experiences and insights in the implementation of the law and of coordinating agency positions on crosscutting policy issues. This report is itself a result of interagency cooperation in the identification and analysis of some common issues. The FLC was created by Congress to provide training in technology transfer to federal laboratory employees, to provide a clearinghouse for technical assistance, to advise and assist the agencies and laboratories with their technology transfer programs, and to facilitate communication and coordination between the federal laboratory technology transfer offices. It carries out these activities through a national management support office, regional coordinators, and an active membership of federal technology transfer professionals.

A more complete description of the way in which the principal agencies have implemented the laws is provided in Appendix A.

Chapter 3: Issues in Federal Technology Transfer

One of the keys to the strength of our economy is our innovation system—our society's ability to generate new ideas and then develop them into new products and services. Part of the strength of this system comes from the complex relationships among American business, federal laboratories, and the nation's research universities. The interactions among these three groups range from the publication of research results to the exchange of scientific and technical personnel, and from public discussions at professional society meetings to cooperative development and licensing of inventions. The purpose of this report is to consider one set of interactions—the ways in which the federal laboratories can work with businesses and other parties under the CRADA and patent licensing provisions of the Bayh-Dole and Stevenson-Wydler Acts. The discussion in this section begins with an examination of the ways in which these mechanisms have affected cooperative activities between the labs and their private sector partners, and concludes with a brief review of cooperation among the laboratories and state and local governments and universities.

One of the keys to the strength of our economy is our innovation system.

Working with the Private Sector: Challenges in Implementing the Technology Transfer Authorities

Since the passage of the Stevenson-Wydler and Bayh-Dole Acts in 1980, representatives of U.S. businesses have helped identify areas for improvement in cooperative activities with the laboratories. They have led groups organized by the agencies to review and assess agency and laboratory procedures and have been important participants in legislative hearings leading to changes in the laws. This section relies, in large part, on the observations of knowledgeable industry representatives to identify challenges to the technology transfer mechanisms. The Office of Technology Policy hopes that this report will lead to a continuing dialogue among the business community and the research agencies concerning these and other challenges to successful research partnerships.

Finding the Right Laboratory

From the outset of federal technology transfer, it has been difficult for private sector partners to identify those laboratories with knowledge and abilities relevant to their needs. For large businesses, corporate staff may be assigned the task of contacting the laboratories to gain information about their strengths and accessibility. Smaller businesses, without resources to invest in such efforts, may not seek access to the laboratories. If they do, they are likely to contact laboratories located near their place of business or where they know a scientist or technologist.

The agencies have begun to address this challenge by creating tools to expedite access to their laboratories. For example, DoD has upgraded its "Techtransit" Web site to provide simpler access to partnering opportunities within DoD.[1] In addition to information about technology transfer programs within the department, the page contains links to DoD's individual laboratories and to specific business opportunities at those laboratories, such as technology available for licensing, cooperative research and development (R&D) opportunities, and other resources. In its recent review of technology transfer policies and procedures, the Department of Energy (DOE) Technology Transfer Working Group identified the need to make "partnership opportunities more accessible, easier to identify and quicker to initiate." The Working Group suggested establishing a "'one-stop-shopping' DOE Home Page Web site for Technology Partnerships with links to all elements of the DOE technology transfer program ... and to all aspects of technology partnering."[2]

The Department of Agriculture's Agricultural Research Service (ARS) provides access to the technologies available for licensing through an online database.

Other agencies, with more centralized technology transfer operations, have also used the Internet to improve access to their partnership and licensing opportunities. The Department of Agriculture's Agricultural Research Service (ARS) provides access to the technologies available for licensing through an online database. Similarly, the National Institutes of Health maintain a Web page that provides access to technologies available for licensing, as well as its policies and standard CRADA and licensing agreements.

It is important that broader guidance be available as well. While each agency aims to meet its internal and perceived external customer needs through its own system of Web sites, many smaller businesses do not know which agencies have expertise in specific technologies. The FLC has attempted to meet this need through a number of information-sharing devices, including newsletters, a Web site, and a laboratory locator service. Its Web site[3] includes links to agency sites, a database search capability based on laboratory missions, and the ability to submit requests to its locator service. The locator service is provided by FLC personnel and helps identify laboratories with expertise in technology areas of interest to the inquiring party. Requests for assistance increased substantially in the past year, and the FLC is working to encourage continued increases in use of the system.

While the FLC's system has been useful to many parties, an even more comprehensive approach may be needed to simplify private sector access

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[1] See http://www.dtic.mil/techtransit/

[2] DOE, *Partnering for Success: A Review of DOE Technology Transfer Policies and Procedures* (June 1999), p. 13.

[3] See http://www.federallabs.org.

to the agencies' research capabilities. With the advances of Internet-based systems for the management of information and knowledge, it should be possible to establish an integrated system providing linkage to all relevant federal sites and databases, although keeping the information timely and current will present a significant problem. It is unclear at this point whether there may also be opportunities for value-added information to be provided on a for-profit basis by private sector information providers.

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Identifying, Protecting, and Managing Intellectual Property at the Laboratories

The management of intellectual property has often been a subject of misunderstanding in research partnerships between the private sector and federal laboratories, although it now seems to be a less frequent and less important issue than at the outset of federal technology transfer. Companies and the laboratories approach the issue from very different perspectives, and the differing provisions of the CRADA and patent licensing laws and regulations add further complexity.

General Attitudes Toward Intellectual Property

Business Attitudes

The Stevenson-Wydler and Bayh-Dole Acts anticipated that the federal laboratories contained technologies that businesses would be able to develop commercially as a source of competitive advantage. While this has proved true in many cases, it has not been the sole motivation for industries to work with the laboratories. In fact, some research has suggested that the private sector regards access to a laboratory's knowledge base on a nonproprietary basis as more important than gaining access to intellectual property resulting from the laboratory's research.

As with most observations concerning federal technology transfer, the answer may well vary from agency to agency and from one scientific discipline to another. For example, a biotechnology or pharmaceutical firm seeking to partner with the National Institutes of Health may well have as its objective gaining access to an innovation that will lead to a new product or therapy. By contrast, airlines entering into a CRADA with the Federal Aviation Administration's research facility are more likely to focus on the development of nonproprietary knowledge that will improve the safety or reliability of their services.

The private sector partner's attitude toward intellectual property issues will be shaped by its objectives in partnering with the laboratory. If the partner is interested mainly in making use of the laboratory's knowledge base, it is not likely to be concerned with intellectual property issues and may, in fact, be partnering with other companies for the purpose of sharing knowledge. Where the firm seeks technology to assist in the development of a new product, it will be concerned with the protection of the technology from unauthorized disclosure and with the reasonableness of the terms and conditions imposed by the agency on the firm's use of the technology. The terms and conditions are particularly important because technologies from the federal laboratories tend to be at a relatively early stage of development and their commercialization requires investments many times greater than initial agency research costs. If the terms and conditions are too restrictive, there will be little incentive to make such large investments.

Agency Attitudes

In some situations, broad access to the technology is the most effective way to ensure widespread use.

The manner in which agencies choose to make their knowledge and inventions available to the private sector is most heavily influenced by their mission responsibilities. In many circumstances, the agency's mission is to encourage the development and diffusion of new technologies into the economy in order to accomplish the agency's objective, such as improved public health or increased agricultural productivity. The critical question is whether patenting will enhance the potential for dissemination and use of the technology. In some situations, broad access to the technology is the most effective way to ensure widespread use. In other situations, the exclusivity provided by a patent may be necessary to encourage its development and use.

In circumstances where commercially valuable technologies are suitable for use without further research or development or need for exclusivity, an agency may work collaboratively with its partners but may share the results of the work broadly (e.g., through nonexclusive licensing or publication of the results). Examples of these kinds of technology transfers can be found in the measurements and standards work of the National Institute of Standards and Technology (NIST),[4] as well as in some

[4] NIST seeks to encourage the adoption of its infrastructure technologies through publication; providing technical support to standards committee work; working with industry consortia; informal technical assistance; prototype construction; public forums and workshops; cooperative work via CRADAs, personnel exchanges, and guest researcher arrangements; and patenting and licensing of the technologies. NIST deems patenting to be appropriate where it enhances the commercialization potential of the technology.

examples from the biomedical and other fields. The United States Public Health Service (PHS), parent agency of NIH, the Food and Drug Administration, and the Centers for Disease Control, has noted that it does not generally seek patent protection "where further research and development is not necessary to realize the technology's primary use and future therapeutic, diagnostic, or preventive uses are not reasonably anticipated."[5] The Department of Agriculture's ARS, with a long and successful history of technology transfer to benefit agriculture and consumers, notes that "[m]any excellent original ideas are best transferred to those who need the information by scientific publications or other methods that do not involve patenting."[6]

In other situations, the dissemination and adoption of the technology may be furthered by seeking patent protection and licensing the resulting intellectual property. Examples of such partnerships frequently occur in the medical and agricultural fields. The private sector is often the source of the funding necessary to take new technologies to markets in the form of commercial products that achieve the public health or agricultural productivity missions of the agencies. PHS has stated that it generally seeks to patent and license technologies "when a patent will facilitate and attract investment by commercial partners for further research and commercial development of the technology."[7] Similarly, while the transfer of agricultural research is often made through publication or public distribution, ARS recognizes that "the public good is best served by also transferring certain discoveries to the private sector for commercialization as an intermediate step in getting the benefits to the ultimate users, farmers and consumers."[8]

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[5] Public Health Service, Technology Transfer Manual, Ch. 200, PHS Patent Policy at http://www.nih.gov/od/ott/

[6] Agricultural Research Service, *Technology Transfer in ARS*, p. 1 (1999).

[7] Public Health Service, *Technology Transfer Manual*, Ch. 300, PHS Licensing Policy at http://www.nih.gov/od/ott/. The Public Health Service has said that it will seek patent protection on biomedical technologies "only when a patent facilitates availability of the technology to the public for preventive, diagnostic, therapeutic, or research use, or other commercial use. Generally a patent is necessary to facilitate and attract investment by commercial partners for further research and commercial development of the technology, such as where the utility of the patentable subject matter is as a potential preventive, diagnostic, or therapeutic product. However a patent also might be necessary to encourage a commercial party to make available for research use important materials or products." Public Health Service, *Technology Transfer Manual*, Ch. 200, PHS Patent Policy at http://www.nih.gov/od/ott/200p06.htm

[8] Agricultural Research Service, *Technology Transfer in ARS*, p. 1.

A third category of transactions involves technologies that are or will be used by the agency in carrying out its mission, but that also have commercial applications. In such circumstances, the mission-related applications (and the competency of the federal laboratories to develop such applications) may be strengthened by participation in research or development relating to their commercial use. Partnerships in this category often involve technologies with both defense and commercial applications, as well as many technologies used by DOE's national laboratories for nuclear and defense purposes. In these circumstances, intellectual property protection and exclusivity in licensing is sometimes necessary to bring about the private sector commitment to develop the technology for commercial use.

The Department of Defense has expressed its support for this type of technology transfer in its directive defining its technology transfer activities. Its directive states, "Consistent with national security objectives under 10 USC § 2501 ..., domestic T2 activities are integral elements of DoD pursuit of the DoD national security mission and concurrently improve the economic, environmental, and social well-being of U.S. citizens...."[9] The three types of technology transfer recognized by DoD are spin-off, dual-use, and spin-on activities, defined in a related DoD instruction as follows:

> Spin-off activities ... shall demonstrate DoD technology; e.g., commercial capability of technologies already developed or presently being developed for U.S. security purposes. The primary purpose of those activities, which encompass T2, shall be to promote and make available existing DoD-owned or [DoD]-developed technologies and technical infrastructure to a broad spectrum of non-DoD applications.
>
> Dual-use science and technology and other activities ... develop technologies that have both DoD and non-DoD applications.
>
> Spin-on promotion activities ... shall demonstrate the U.S. security utility of technologies developed outside of the Department of Defense. That goal shall be to incorporate the innovative technology into military systems to meet mission needs at a lower acquisition cost by taking advantage of the economies of scale by purchasing from a larger industrial base.[10]

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[9] DoD Directive 5535.3 (May 21, 1999), available at http://www.dtic.mil/technntransit/

[10] DoD Instruction 5535.8 (May 14, 1999), available at http://www.dtic.mil/technntransit/

Summary

It is important for each side of the partnership to understand the other's perspective. The private sector partner's objectives may range from tapping the general knowledge base of the laboratory for nonproprietary applications, to securing exclusive access to laboratory research to develop a new product. In the latter circumstances, the partner will be concerned with preserving preferential access to the innovation and securing the most favorable terms and conditions for the time consuming and expensive development of commercial applications. By contrast, the agency will be primarily concerned with how the transfer of the technology helps to accomplish its mission, as well as with compliance with the legal requirements imposed on its interactions with the private sector.

The private sector partner's objectives may range from tapping the general knowledge base of the laboratory for nonproprietary applications, to securing exclusive access to laboratory research to develop a new product.

Intellectual Property and the CRADA

The Stevenson-Wydler Act anticipates that intellectual property may be created by the CRADA collaboration. It gives the laboratory director authority to negotiate licensing agreements, under the provisions of the Bayh-Dole Act or other authorities, for lab inventions or "other intellectual property developed at the laboratory." The law was amended in 1996 to ensure that the CRADA partner received sufficient rights to intellectual property to warrant the investments needed for commercialization. The laboratory is now required to ensure the private sector partner "has the option to choose an exclusive license for a pre-negotiated field of use for any such invention...."[11]

As discussed earlier, the extent to which inventions are produced as a result of CRADA work seems to vary widely. Our general survey of the agencies suggests that relatively few inventions have required the use of the licensing provisions discussed above. On the other hand, NIH reports that intellectual property is being generated at approximately the same level in CRADA research as in non-CRADA research—about 15 percent of projects. In addition, there may be other reasons why licensing of inventions may not occur. It seems reasonable to anticipate that the private sector partner may be a co-inventor in many cases and have no need for a license from the laboratory. Even if a license is needed, the partner may delay the licensing decision until later to avoid paying a licensing fee at the same time it is supporting the CRADA.

[11] Public Law 104-390 amending 15 USC § 3710a(b)(1).

Where intellectual property arises under the CRADA agreement, several areas of confusion may occur. The first involves the question of whether the licensing of such intellectual property is subject to the procedural requirements of the patent licensing provisions of the Bayh-Dole Act—particularly the requirement that notice and an opportunity to object be given where an exclusive license is contemplated. The agencies generally do not interpret the government patent licensing law and regulations as requiring the publication of notices for exclusive licenses or the application of other requirements of those regulations to inventions occurring under the CRADA.

A second area of confusion is sometimes created by the application of the concept of "subject inventions" in connection with the work. CRADA agreements typically provide that both sides shall have certain defined rights in "subject inventions," a concept which usually includes any invention "conceived or first actually reduced to practice in the performance of work" under the CRADA. This concept is contained in the definition of "made" in the Stevenson-Wydler Act[12] and is identical to the language of the Bayh-Dole Act, in which the term is used to describe the category of inventions for which a nonprofit organization or small business may elect to retain title.[13]

The concept may create confusion where an invention, already conceived by one of the parties prior to the CRADA, is first reduced to practice as a part of the CRADA work. In particular, where the private sector partner to the CRADA first reduces a preexisting invention to practice during the CRADA, the government partner may assert that the invention has become a "subject invention" in which it is entitled to certain rights, such as a license to use the patent for governmental purposes. Some agencies attempt to address this issue by defining "subject inventions" under a CRADA as relating only to inventions "conceived" under the CRADA, eliminating those first reduced to practice under the agreement.

Intellectual Property and Agency Patent Licensing

The agency attitudes toward intellectual property discussed above will influence its decision whether to patent a laboratory invention and will influence the terms under which such patents may be licensed. The Bayh-Dole Act specifies a number of factors that the agency must consider

[12] 15 USC § 3703(9).

[13] 35 USC § 201(e).

when granting a license and also prescribes procedures for the licensing process. The procedures for granting exclusive licenses have been the most frequent source of misunderstanding between the agencies and the business community.

In order to be considered for a license, an applicant must present the agency "with a plan for development and/or marketing of the invention." [14] This plan provides a factual basis to which the agency may apply the statutory criteria governing the licensing decision. These criteria require a number of different determinations by the agency before the license may be granted. The process for granting an exclusive license includes additional requirements.

In granting an exclusive or partially exclusive license, the agency must first provide public notice of its intention to grant the license and an opportunity for others to file written objections to the license. It must then determine that both the government's interest and the public interest "will best be served by the proposed license, in view of the applicant's intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention's utilization by the public." The agency is also required to determine that exclusivity is necessary to achieve practical application of the invention and that exclusivity is "a reasonable and necessary incentive to call forth" the investment needed to achieve practical application or promote utilization of the invention. Finally, the agency must determine that "the proposed terms and scope of exclusivity are not greater than reasonably necessary to provide the incentive for bringing the invention to practical application or otherwise promote the invention's utilization by the public." [15]

These detailed criteria for granting exclusive licenses reflect some of the same considerations noted in discussing the role that agency missions play in determining attitudes toward technology transfer. Agencies such as NIH and the ARS place a special emphasis on the need to limit exclusivity to those circumstances where it is needed to encourage commercial development of the licensed technology. They note that a technology may have multiple applications but that a company applying for an exclusive license to all of those applications may have competence in only one. In those circumstances, the agencies believe that granting an exclusive license to an applicant firm that cannot pursue the commercial development of all of the applications may prevent those other applications from

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[14] 35 USC § 209(a).

[15] 35 USC § 209(c)(1)(A)-(D).

being developed and new products being brought to market. For these reasons, they limit licensing to those applications for which a company has a viable commercial plan and the capability to develop those applications into products.

Confidentiality and Licensing of Information Generated by a Laboratory under a CRADA

One aspect of intellectual property management under a CRADA that has received relatively little attention is the treatment of information developed by a laboratory in the conduct of work under the CRADA. Congress has authorized the laboratories to identify and protect, for up to 5 years, certain laboratory information resulting from CRADA research activities. The information may be protected if it is of a type that would be "a trade secret or commercial or financial information that was privileged or confidential if [it] had been obtained from a non-Federal party...."[16] Some laboratories have used this provision as a basis for granting a CRADA partner exclusive access to CRADA information for up to 5 years for the purpose of its commercial development.

The use of the confidentiality protection has generally been limited to those circumstances where the laboratory data truly require such protection. Where the focus of the CRADA is on nonproprietary research, with no use of proprietary corporate data and little anticipation of resulting intellectual property, there is little reason to restrict access to the data generated by the work. However, where proprietary corporate data is used or intellectual property results from the work, there may be value in protecting CRADA-generated information, as well as any inventions. Where this approach has been used, the laboratories have periodically assessed the information produced by the CRADA work in cooperation with their private sector partners (as is done with invention disclosures). The purpose of the assessment is to see if it the CRADA-generated information has matured to the point where patenting is appropriate or if protection from disclosure is still justified.

Some recent litigation generally affirms the agency's ability to protect CRADA information but also suggests some limits, especially in the case of general information generated by the agency. In *Delorme Publishing Co.*

[16] 15 USC § 3710a(c)(7)(B).

v. NOAA, 917 F.Supp. 867 (D. Me. 1996), the court agreed that the National Oceanic and Atmospheric Administration (NOAA) was not required to disclose CRADA files in response to a Freedom of Information Act request. NOAA had designated the files, which contained data used to generate nautical maps and included information developed by NOAA prior to but in contemplation of the CRADA, as confidential under the CRADA provisions. NOAA's CRADA partner then used the data to generate its own set of nautical maps that it sold commercially.

Limits to the types of data that can be protected under the CRADA laws are suggested by a related ruling, *Maptech, Inc. v. Pinpoint Systems Int'l, L.L.C.* (C. D. Cal. 1999). In Maptech, NOAA's private sector CRADA partner sued another firm, alleging that it was selling nautical maps identical to those the partner had produced using the confidential NOAA CRADA data. The *Maptech* court found that the CRADA map data were "government works, and as such are not entitled to any copyright protection" and declined to enjoin the third party's sales of its maps. The court's opinion suggested that any claim that the data were protected under the CRADA provisions would require an examination of the time periods involved (confidentiality may not be granted for more than 5 years) and of the nature of the data (the data may be protected only if they would be confidential if obtained from a private party).

A more elaborate approach advanced by some laboratories builds on the Stevenson-Wydler Act's statement that the agencies and their laboratories "may negotiate licensing agreements under section 207 of Title 35, or under other authorities ... for inventions made or other intellectual property developed at the laboratories."[17] It is argued that the confidential information generated under the CRADA should be regarded as "other intellectual property" and, therefore, licensable. While the authority for such licensing is not explicit in either the Bayh-Dole Act or the Stevenson-Wydler Act, the confidentiality provisions of the Stevenson-Wydler Act have been cited as a basis for licensing the laboratory's information, at least within the 5-year period authorized by that law. In such an approach, the laboratory would presumably be required to accord the CRADA partner the same rights to an exclusive license on such information as the lab would accord for laboratory inventions.

[17] 15 USC § 3710a(a)(2).

The government seldom uses its licenses arising from inventions by universities under the Bayh-Dole Act.

Government Licenses to Private Sector Inventions

Another issue cited by business observers relates to the government's practice of claiming a license to inventions made by a private sector party under a CRADA or other technology transfer agreement with a federal laboratory. The Stevenson-Wydler Act requires the agencies to ensure that the government is normally granted a license to practice or have practiced on behalf of the government any invention made by the collaborating party.[18] The use of the word "normally" in the 1996 amendment to the Stevenson-Wydler Act was intended to give the agencies discretion to forego the license to the government. Under the Atomic Energy and Space Acts, DOE and NASA may take title to inventions made under practically any type of arrangement, although these laws also state that the agency may waive these rights.[19] In practice, however, business representatives complain that the government almost always retains a government license.

As a recent Government Accounting Office report noted, it appears that the government seldom uses its licenses arising from inventions by universities under the Bayh-Dole Act, and it is reasonable to expect a similar situation with respect to agency rights to CRADA inventions.[20] In some instances, it may make sense for the government to retain a research license. However, if the technology being developed under a CRADA is based upon a company's proprietary technologies or its declared background intellectual property, the case for waiving all government rights is strengthened. Alternatively, the license might be limited to the mission purposes of the agency, such as to protect public health and safety.

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[18] 15 USC § 3710a(b)(2) requires a laboratory entering into a CRADA to "ensure that a collaborating party may retain title to any invention made solely by its employee in exchange for normally granting the Government a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government for research or other Government purposes."

[19] 42 USC § 2457 (NASA); 42 USC § 2182 (Energy).

[20] GAO, *Technology Transfer: Reporting Requirements for Federally Sponsored Inventions Need Revision.* RCED-99-242, Aug. 12, 1999. The report identified a number of circumstances interfering with the agencies' ability to make use of such licenses, such as the failure of the research organizations to provide necessary information, and the fact that the patented technology is only a part of a final product sought by the agency.

Recognizing the Diverse Uses of CRADAs

The CRADA mechanism was intended by Congress to be flexible enough to meet the diverse needs of the private sector and the agencies in performing cooperative research. With this objective in mind, it was placed outside the usual categories of government research agreements (i.e., contracts, grants, and cooperative agreements) and outside the scope of agency regulations governing those agreements. As a result, CRADAs have been used in many different ways and for many different purposes by the agencies and their private sector partners in the past 12 years.

The discussion in this section begins with recognition that there are circumstances in which the CRADA is not appropriate, such as where it is used as a substitute for a contract. In the remainder of the section, the continuum of research relationships covered by CRADAs is discussed and their differences noted. While it is important to preserve the flexibility of the CRADA to cover all of these situations, it is also important for the agencies and their partners to recognize the diverse ways it has been successfully employed and the need to suit the terms of the agreement to the uses intended by the parties.

Legal Limits to the Use of CRADAs

Several possible limits on the use of CRADAs have been suggested in litigation. One case suggests that the use of a CRADA as a substitute for a normal contractual agreement may be suspect, especially where there appears to be little collaborative research involved. The Environmental Protection Agency (EPA) entered into a CRADA to develop, produce, and distribute some EPA standard reference chemicals and was sued by a company that had sought to participate in the CRADA but had not been selected. The appellate court ruled that the reference chemicals to be distributed via the CRADA had previously been made available to the public through contract and ruled that EPA appeared to be bypassing the procurement laws in its use of a CRADA for this purpose.[21] The case was settled before any further decision was rendered.

A second legal challenge, involving a CRADA entered into by the National Park Service (NPS), also appears to suggest the importance of cooperative research as the focus of the CRADA. *Edmonds Institute v. Babbitt*, 42 F.Supp 2nd 1 (1999), involved a CRADA awarded in 1997 by the Interior Department's NPS. The purpose of the CRADA was to allow

[21] *Chem Serv., Inc. v. Environmental Monitoring Sys. Lab.*, 12 F.3rd 1256 (3rd Cir. 1993).

Today many different types of research relationships are encompassed within the CRADA agreement.

the corporate partner to sample microorganisms at Yellowstone National Park, which it would then analyze for possible medical uses. The CRADA required the partner to share with NPS any revenue received in connection with drugs derived from such microorganisms. The court refused to dismiss the claim that NPS's use of a CRADA violated the Federal Technology Transfer Agreement and stopped further work under the CRADA until an environmental assessment was conducted by the agency.[22]

The Extensive Range of Research Relationships Covered by CRADAs

Today many different types of research relationships are encompassed within the CRADA agreement. These relationships are a function of differing agency mission objectives, differing private sector research objectives, and differing levels of development of the technology that is the subject of the CRADA.

Agencies interested in achieving a broad dissemination of the technology being researched may favor the publication of project results. Where the dissemination of the research is likely to take place through the marketing of commercial products and services, the agency is more likely to support the patenting or confidential treatment of the project results. Industry's perspective is likely to be shaped largely by the degree to which it is willing to share proprietary information with the laboratory as a part of the project and its need for intellectual property rights or exclusive access to project results to encourage commercialization. The variables and corresponding levels of contractual engagement might be expressed in three different types of arrangements:

1. Nonproprietary CRADAs: The laboratory is pursuing mission-related R&D not requiring confidentiality or intellectual property protection for mission purposes. Companies wish to participate in the research but do not view confidentiality or intellectual property protection as necessary to protect their interests. The parties wish to share the results of the work either

[22] The court also questioned whether NPS was a laboratory as that term is defined in FTTA. Although the government did not appeal the injunction, there are still a number of issues to be resolved. The plaintiff also sued NPS under the Freedom of Information Act to obtain a copy of the financial terms of the NPS CRADA. No decision has yet been handed down on these aspects of the case.

through written reports or nonproprietary technical briefings. The companies provide support for the work, critique it as it proceeds, and propose additional matters to be pursued.

2. First-level Proprietary CRADAs: The laboratory is pursuing mission-related R&D that aligns with the commercial needs of a company. The laboratory's mission is best accomplished through the commercialization of the technology and its use to produce new products and services, either because availability of the product or service will advance the mission or because development of the product or service will enhance other mission-related uses of the technology. Most of the work will be based upon the laboratory's own knowledge base, and the company will provide funding and participate in the research. The objective of the company is to gain a competitive, and hopefully proprietary, advantage as a result of the project, based upon intellectual property and the company's own product and market knowledge, some of which is shared with the laboratory.

3. Second-level Proprietary CRADAs: The laboratory has a special competence or knowledge base, developed for mission purposes, that is needed to advance a specific aspect of the company's commercial work. Both parties bring intellectual property to the project, and the company funds at least a portion of the laboratory efforts. The agency's mission will best be advanced by the development of the technology into commercial products or services. There will be close collaboration, and the parties will aggressively protect any intellectual property generated by the work.

Although there are many possible variations on these three examples, they serve to illustrate the different levels of engagement that may be encompassed within CRADAs. In practice, some companies have actually moved through all three levels in pursuing a technology development at a laboratory, although the CRADA instruments covering the work contained nearly identical provisions.

At some laboratories, the first example above could possibly be accomplished through informal interactions, without the use of a CRADA. But at others, such as a DOE Defense Programs laboratory, the lack of a CRADA could create problems for the private sector firms because of

DOE's unique statutory authority to assert ownership rights to inventions arising even under informal industry/laboratory arrangements.[23]

If the diverse uses of the CRADA mechanism are to be recognized, the agencies must be certain these "models" have the flexibility needed to meet these differing circumstances.

The agencies have attempted to expedite the negotiation process by developing "model" CRADAs for use by their laboratories. If the diverse uses of the CRADA mechanism are to be recognized, the agencies must be certain these "models" have the flexibility needed to meet these differing circumstances. For example, the intellectual property provisions, which are often the most time-consuming provisions to negotiate, might be extremely simple at the first level of engagement discussed here, enabling the parties to put an agreement in place more quickly.

Another area that might be both simplified and rationalized between agencies relates to the financial commitments required of private sector participants. Some laboratories, particularly the DOE government-owned, contractor-operated (GOCO) laboratories, are required to secure an industry "match" in funding equal to at least 50 percent of the total cost for the project. In the "nonproprietary CRADA" example, where one or more companies have a general interest in the laboratory's mission-related work, the financial contribution of the private sector participant(s) is not likely to meet the funding requirement. In this and other instances, a commonsense approach to private sector spending commitments would be to base the rights on the contributions (financial and in-kind) made by the parties.

Other Types of CRADAs

Several other types of CRADAs have proved useful in achieving the goals of the technology transfer laws. These include the "blanket" CRADA and the "technical assistance" CRADA.

Several other types of CRADAs have proved useful in achieving the goals of the technology transfer laws. These include the "blanket" CRADA and the "technical assistance" CRADA. The DoD recognized these variations in a recent report, expressing support for their use.[24]

The "blanket" or "umbrella" CRADA is designed to encourage the development of relationships between a laboratory and businesses of a specific type or in a specific region. These agreements may be entered into with an organization that represents a broader group of businesses, within either a specific sector or a specific geographical region. The "blanket" agreement makes it easier for the individual businesses that are members of the organization to become acquainted with the laboratory and its expertise, with the hope that such acquaintance will ripen into more ambitious cooperative research efforts.

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[23] 42 USC § 2182.

[24] DoD, *Cooperative R&D Agreements: Value Added to the Mission,* April 1999, at http://www.dtic.mil/techtransit

A "technical assistance" CRADA is somewhat similar, creating a relationship between a laboratory and a local or regional organization concerned with the competitiveness of the businesses in its area. The CRADA creates a structure for the efficient delivery of technical assistance by the laboratories to the individual businesses represented by the local or regional organization.

In both of these types of agreements, the relationships created are relatively simple and the complex issues of intellectual property discussed earlier are unlikely to arise. Development of "model" agreements for these two categories of cooperation might help to further their use and to broaden the scope of federal technology transfer.

The process of negotiating CRADAs and patent licenses has become simpler for both businesses and government partners as they have begun to understand one another's needs and constraints.

Dealing with U.S. Competitiveness Concerns and Product Liability Issues

The process of negotiating CRADAs and patent licenses has become simpler for both businesses and government partners as they have begun to understand one another's needs and constraints. However, there are still several areas in which the business community has difficulty understanding and accepting clauses that the laboratories seek to include in technology transfer agreements. The principal concerns relate to clauses designed to protect U.S. competitiveness and those governing the liability of the government in connection with the agreement. In the case of U.S. competitiveness, the concerns often relate to the complexity of the requirements and the apparent lack of flexibility in the criteria applied by the laboratories. In the case of the liability and indemnification clause, the concerns generally arise from the strictness of the clauses and the agencies' inability to offer alternatives.

U.S. Competitiveness Provisions

The CRADA and licensing authorities attempt to ensure domestic advantage from the development of the transferred technology. Both the Bayh-Dole and Stevenson-Wydler Acts encourage the domestic manufacture of products embodying the invention when those products are sold for domestic consumption. Where a foreign party is involved in the transaction, additional requirements encourage domestic access to foreign research collaborations, foreign protection of intellectual property, and foreign export controls.

The precise application of these requirements is made more complicated by the differences in treatment of government-owned, government-

operated (GOGO) laboratories and GOCO laboratories. Many of the large DOE laboratories, such as Los Alamos, Sandia, and Livermore, along with Federally Funded Research and Development Centers (FFRDCs), such as NASA's Jet Propulsion Laboratory, fall into the GOCO category.

Intellectual Property Licensing with International Aspects

Licensing of Intellectual Property from Government-operated Laboratories

In the case of intellectual property owned by a federal agency (as in the case of inventions arising in GOGO laboratories), the Bayh-Dole Act requires that the agency "normally" grant rights only to a licensee that agrees to manufacture substantially in the United States "any products embodying the invention or produced through the use of the invention."[25] The statute does not define the phrase "manufacture substantially." The statement that such a requirement shall "normally" be imposed has been interpreted by the agencies to mean that exceptions to the "substantial manufacture" test may be allowed, although the criteria for such exceptions are not stated in the law.

The law and implementing regulations include several other provisions that may be important in the international context. They provide a preference for small business licensees and, in fact, the majority of licenses entered into by the agencies are with small businesses. They also require the giving of public notice when an agency is contemplating the granting of an exclusive license, thus affording interested parties an opportunity to seek a license or to oppose the proposed grant of exclusivity. In the agencies' experience, the notice procedure has been extremely useful in helping to discharge their licensing responsibilities and, in some instances, to identify small domestic firms able to commercialize the technology better than are larger domestic and foreign applicants.

Licensing of Intellectual Property from Contractor-operated Laboratories

Domestic manufacture requirements are also imposed on the licensing activities of entities operating GOCO laboratories, although with some small legal differences. In addition, there are some minor differences between GOCO laboratories operated by nonprofit organizations (e.g., universities) and those operated by for-profit entities. If the operator of the laboratory is a nonprofit organization, it is able to claim rights to its inventions under the Bayh Dole Act and license those rights as provided for by that law. The domestic manufacture provisions of the Bayh-Dole

[25] 35 U.S.C. § 209(b).

Act applicable to nonprofit organizations provide that neither such entities, nor their assignees:

> shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency under whose funding agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.[26]

This language contains a clearer recognition than the law governing agency licensing that the domestic manufacture preference may need to be waived in certain circumstances, and also provides a clearer statement of the basis and procedure for such waivers (as opposed to the GOGO language discussed above).

Finally, some special considerations apply to the GOCO laboratories operated for DOE by their contractors. In the case of most of its GOCO laboratories, DOE provides the operators with rights similar to those granted under the Bayh-Dole Act, but on the basis of patent waivers granted by DOE. These waivers impose requirements of substantial manufacture in the United States, consistent with the requirements applicable to other federal laboratory operators.

Executive Order 12591

A second set of procedural requirements applicable to all licensing transactions is contained in Executive Order 12591.[27] That order, based on the Federal Technology Transfer Act, the Bayh-Dole Act, and other executive orders, contains special provisions designed "to ensure that the United States benefits from and fully exploits scientific research and technology developed abroad" in instances where CRADAs or licensing arrangements are negotiated with foreign persons or industrial organizations. The order defines this category of foreign persons as "foreign

[26] 35 U.S.C. § 204.

[27] 52 Fed. Reg. 13414 (April 10, 1987).

The CRADA laws deal with international competitiveness issues by requiring the agencies to give preference to businesses located in the United States that agree to substantial domestic manufacture of resulting products.

persons or industrial organizations (where these entities are directly or indirectly controlled by a foreign company or government)."[28]

In transactions involving such persons, agencies are directed to "give appropriate consideration" "in consultation with the United States Trade Representative" to several different factors:

1. whether such foreign companies or governments permit U.S. participation in comparable cooperative research and licensing arrangements,

2. whether the foreign governments "have policies to protect the United States intellectual property rights," and

3. whether the foreign governments have "adequate measures" to prevent unauthorized transfers of technologies subject to U.S. national security export controls.

CRADAs with International Aspects

A second set of laws governs the use of Cooperative Research and Development Agreements (CRADAs) by the federal GOGO and GOCO laboratories. Once again, there are differences in the standards and procedures for the two categories of laboratories, and some special procedural requirements for DOE laboratories.

The CRADA laws deal with international competitiveness issues by requiring the agencies to give preference to businesses located in the United States that agree to substantial domestic manufacture of resulting products. The agencies read this language as effectively requiring that a domestic manufacture requirement be included in the CRADA, subject to the same possible exceptions already noted.[29] Although the procedures for exceptions to this requirement are not addressed in the statute, some

[28] E.O. 12591, Sec. 4(a).

[29] The agencies are required to "give preference to business units located in the United States which agree that products embodying inventions made under the cooperative research and development agreement or produced through the use of such inventions will be manufactured substantially in the United States and, in the case of any industrial organization or other person subject to the control of a foreign company or government, as appropriate, to take into consideration whether or not such foreign government permits United States agencies, organizations, or other persons to enter into cooperative research and development agreements and licensing agreements." 15 U.S.C. § 3710a(c)(4)(B). The second part of this requirement is substantially similar to one of the requirements of E.O. 12591.

agencies have attempted to formulate standards and procedures to govern such decisions.[30]

Once a CRADA is entered into, the laboratories are authorized to "negotiate licensing agreements" pursuant to the authorities of the Stevenson-Wydler Act for CRADA-generated intellectual property.[31] These licensing agreements trigger the "substantial manufacturing" requirements and other procedural requirements relating to agency licensing of intellectual property discussed in the preceding section. The requirements of Executive Order 12591, discussed in the preceding section, are also applicable to CRADAs.

The CRADA process has several special requirements applicable to GOCO labs. Time limits are set for the approval of GOCO CRADAs (and the related joint work statements used by the DOE laboratories as a preliminary step to CRADAs).[32] In addition, because of the complexity of the process when GOCO laboratories are involved, agencies with GOCO laboratories are required to develop "one or more model cooperative research and development agreements, for the purpose of standardizing practices and procedures, resolving common legal issues, and enabling review of cooperative research and development agreements to be carried out in a routine and prompt manner." Pursuant to this requirement, DOE has developed and given broad circulation to a model CRADA that has optional clauses designed to meet the different types of cooperative activities and/or needs of the private sector participants.[33]

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[30] See DOE Model CRADA, Art. XXII.

[31] More specifically, the laboratory is obligated "to grant, or agree to grant in advance, to a collaborating party patent licenses or assignments, or options thereto, in any invention made in whole or in part by a laboratory employee under the agreement, for reasonable compensation when appropriate." 15 U.S.C. §3710a(a)(2) and (b)(1).

[32] The joint work statement, which must clearly identify foreign entities formally involved in a CRADA, must be submitted to the DOE for approval prior to the execution of the CRADA and must be approved or rejected for cause by the DOE within 90 days. The resulting CRADA must be reviewed by the DOE and, if fully compliant with the joint work statement and approved terms and conditions, be approved for signature by the laboratory director within an additional 30 days after being submitted to the DOE by the laboratory. 15 USC § 3710a(c)(5)(C).

[33] See http://www.gc.doe.gov/gc-02/crada/toc.htm

Defining the domestic economic benefits that must be present in any cooperative research relationship or intellectual property license is both politically sensitive and factually demanding.

Industry Concerns

The principal private sector concern has been the domestic manufacture requirement generally imposed in both licensing and CRADA transactions. Many firms with extensive international operations have stated that they are unable to make commitments years in advance concerning the place of manufacture of products that may emerge from these collaborations, emphasizing the shifting and fluid nature of the international supply chains used to produce their products. They also suggest that the principal economic benefit relating to the development of new products and services may come from hosting the research and development in the United States, rather than from conducting the manufacturing process domestically. Finally, the lack of clear and uniform decisional criteria for the waiver of these provisions may cause agency and laboratory decisions to appear arbitrary to the business community. As a result, many companies, particularly those with extensive international production operations, may find it difficult to enter into technology transfer agreements with a federal laboratory.

Defining the domestic economic benefits that must be present in any cooperative research relationship or intellectual property license is both politically sensitive and factually demanding. Nevertheless, the increasingly global nature of commerce and the emerging importance of federal technology transfer may make such a resolution necessary to effective use of the transfer mechanisms.

Indemnification and Product Liability

Many CRADA and license agreements offered by a federal laboratory to a prospective CRADA partner or licensee contain language requiring that the private sector partner indemnify the government against any liability that might arise from the research work or from products ultimately resulting from that work. One such clause provides:

> Except for any liability resulting from any negligent acts or omissions of Contractor, Participant indemnifies the Government and the Contractor for all damages, costs and expenses, including attorney's fees, arising from personal injury or property damage occurring as a result of the making, using or selling of a product, process or service by or on behalf of the Participant, its assignees or licensees, which was derived from the work performed under 14 December 14, 1995 this CRADA. In respect to this Article, neither the Government nor the contractor shall be considered assignees or licensees of the Participant, as a result of reserved Government and Contractor rights....[34]

[34] Article VI, Department of Energy Modular CRADA, at http://www.gc.doe.gov/gc-02/crada/art6.htm

In a litigious society, private sector firms are sensitive to the legal and financial risks arising from product liability and to the potential burden of such an indemnification requirement. For this reason, companies entering into technology transfer transactions with the agencies and laboratories often hesitate to agree to indemnification and product liability clauses offered by the agencies. The result is often extensive delays, additional costs for the company (particularly for small businesses that pay hourly fees to outside attorneys) and strained relations between the parties that may continue even after the work on the project begins.

Many agencies and laboratories have been unwilling to show flexibility in addressing this issue, arguing that the government must be protected from any liability arising out of the commercial activities of the company. At the same time, there has been no litigation in which such CRADA-related liability has been asserted against an agency.[35] In these circumstances, it does not seem unreasonable for the agencies to show some flexibility concerning this clause, especially in the case of nonprofit and small-business partners. Defusing this issue early in the negotiations might lower anxiety levels and minimize the potential for later negative impacts on the negotiations.

Working with Other Public Sector Institutions

The Stevenson-Wydler Act encourages federal laboratories to use their CRADA authority as a mechanism to work more closely with state and local governments and with universities. However, attention over the years has focused on federal laboratory collaborations with the private sector. The benefits and challenges of partnering with other public institutions have not been as well explored. Because such partnerships are an essential part of our technology infrastructure, it is important to have a better understanding of the ways in which the agencies have used them.

[35] Since CRADAs do not contain an "Authorization and Consent" clause waiving sovereign immunity, it is not clear that the government could be liable for any patent or copyright infringement or liable on the basis of any theory of product liability even in the absence of the proposed clause.

Most agencies and their laboratories have close relationships, both institutional and individual, with the university community.

Federal Laboratory Interactions with Universities: Intellectual Property Issues

In passing the Stevenson-Wydler Act, Congress observed:

> Many new discoveries and advances in science occur in universities and federal laboratories, while the application of this new knowledge to commercial and useful public purposes depends largely upon actions by business and labor. Cooperation among academia, Federal laboratories, labor, and industry, in such forms as technology transfer, personnel exchanges, joint research projects, and others should be renewed, expanded, and strengthened.[36]

Most agencies and their laboratories have close relationships, both institutional and individual, with the university community. Most regularly fund university research, and many regularly host visiting university researchers—both professors and graduate students. In addition, many federal researchers hold adjunct positions on university faculties. As noted in the discussion of individual agency technology transfer efforts, many agencies have used the other partnership authorities available to them to create research partnerships with universities.

Within the Department of Defense, the three Services have emphasized the use of Educational Partnership Agreements. To date, DoD has over 200 formal partnerships with universities and community colleges as well as local public school districts. These partnerships, as defined under 10 USC § 2194, are formal agreements between a laboratory and an educational institution for the purpose of transferring or enhancing technology applications, providing technical assistance, exchanging personnel, or lending or donating educationally useful laboratory equipment for all levels of education.

NIST has entered into a Memorandum of Understanding with the University of Maryland and Montgomery County, Maryland, to create the Center for Advanced Research in Biotechnology (CARB) in Rockville, Maryland. CARB allows academic, government, and industry scientists to work together in a modern facility on problems of the greatest importance to biotechnology research in the field of protein structure, function, and design. It also provides an ideal setting for the training of graduate and postdoctoral students. The nearby location of many biotechnology firms, as well as the laboratories of the National Institutes of Health and NIST, also enables the center to work with industry through personnel

[36] 15 USC Sec. 3701 (3)

exchanges, support of the center's research programs, and other relationships negotiated on a case-by-case basis.

NIST has created a similar partnership with the University of Colorado at Boulder, originally named the Joint Institute for Laboratory Astrophysics and now known simply as JILA. JILA's mission now includes the development of new measurement methods and standards, the improvement of industrial competitiveness, and the education of graduate students in technology. It is a center for collaborative research, with a fellowship program bringing distinguished scientists from around the world to the institute. JILA also brings industry visitors to its facilities and applies its technical expertise to help solve technical problems facing U.S. companies.

Although many partnerships have been created between the laboratories and universities, the data gathered for this report indicate that relatively few federal laboratories have entered into CRADAs with universities. The explanation most often offered for the lack of CRADAs with universities relates to the apparently conflicting approaches to intellectual property management under the Bayh-Dole and Stevenson-Wydler Acts.

Under the Bayh-Dole Act, a university may generally retain title to any invention made in the conduct of federally funded research. While a funding laboratory or agency may deny those rights in "exceptional circumstances," laboratories and agencies are reluctant to do so, because they need the knowledge of the university researchers and those researchers are unlikely to participate if they do not receive their Bayh-Dole rights. In the case of a CRADA with a private sector partner, however, the situation may become more complicated, because the Stevenson-Wydler Act requires the laboratory to offer the business partner an option to license technology generated by the government under the CRADA. If a university is a sole or joint inventor of technology under the CRADA, the government would not be able to provide its partner with rights to the university inventions. Several solutions to this problem have been pursued by the agencies. For example, where the private sector partner funds the university work, the provisions of the Bayh-Dole Act are inapplicable. Even when the funding comes from the agency, the issue may be addressed by negotiation of an agreement between the university and the private sector partner, providing an option for an exclusive license to any inventions on terms consistent with the agency's obligation. While these and other approaches may avoid the

Under the Bayh-Dole Act, a university may generally retain title to any invention made in the conduct of federally funded research.

problem of fragmentation of intellectual property rights, many laboratories nevertheless appear reluctant to include universities or other entities with Bayh-Dole rights in their CRADAs.[37]

Federal Laboratory Interactions with State and Local Governments

One of the reasons for the Stevenson-Wydler Act was to provide formal authority for the laboratories to work more closely with state and local governments. The Act states that "it is in the national interest to promote the adaptation of [laboratory] technological innovations to State and local government uses. [Such t]echnological innovations can improve services, reduce their costs, and increase productivity in State and local governments."[38] The laboratories have continued their traditional, informal cooperation with local government entities and many are now working successfully with both state and local governments to support economic development through CRADAs and a variety of other mechanisms.

One example of the successful linking of laboratories to state and local economic development initiatives is the Technology Ventures Corporation (TVC), founded in 1993 by Lockheed-Martin, operator of the DOE's Sandia National Laboratory in Albuquerque, New Mexico. TVC was established as a nonprofit economic development company to assist in moving commercially valuable technologies from Sandia to the private sector. In less than six years, 36 new companies have been started in and around Albuquerque, including 22 based on Sandia technology. Over $134 million in investment capital has been raised by client companies and over 1900 new jobs have been created. In addition, nearly 500 private sector firms have turned to TVC for technical or business assistance. In a July 1999 report on regional economic development, the Milken Institute identified Albuquerque as having the fastest growing high-technology output in the country. Some of that success has been attributed to TVC's work.

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[37] A related problem has arisen with respect to those GOGO laboratories that rely on contractors to perform some laboratory work. In an era of shrinking budgets, GOGO laboratories are increasingly reliant on the use of contractors to carry out routine laboratory tasks. If these contractors are tasked to carry out work in connection with a CRADA, it is possible that the contractor might become an inventor or co-inventor of inventions, entitled to claim title to them under federal law, thus frustrating the laboratory's ability to provide its private sector partner with rights to all inventions arising under the CRADA.

[38] 15 USC § 3701(9)

Another interesting example of collaboration aimed at achieving economic development and involving a federal agency, state and local government, universities, and industry is the Biotechnology Research and Development Corporation (BRDC). BRDC resulted from the collaborative efforts of the Department of Agriculture's Northern Regional Research Center, local government authorities in Peoria, Illinois, and a number of private sector companies interested in agricultural technologies. BRDC currently has 10 publicly traded companies as shareholders. It helps to fund collaborative research at the Agriculture Research Service's (ARS) laboratories and 26 universities, looking for embryonic technologies that it can push to proof of concept. Early-stage commercial development is generally handled by finding a suitable private sector partner to work with the inventors (generally a BRDC shareholder but sometimes a BRDC licensee). During 1998, BRDC filed 11 new patent applications, had 24 patents issued or applications allowed, and executed eight license and option agreements.

Many interesting and important technical achievements have come out of BRDC-backed research.

Many interesting and important technical achievements have come out of BRDC-backed research. ARS scientists, working with Dow Chemical Company scientists, have developed a family of composite materials derived from starches and flours that exhibit remarkable mechanical and strength properties and can be fabricated into injection and compression molded and extruded articles. Rights to certain uses of the materials have been licensed to Dow. BRDC also funded research at Purdue University producing a plant gene promoter useful in genetically engineered crops and has granted licenses or options to license to nearly every major agriculture biotechnology company in the world, as well as making it available to researchers. This technology has generated more than 50 percent of BRDC's licensing income. BRDC, in collaboration with the University of Illinois, has also filed for the first patent on stem cell technology involving an animal other than the mouse. This technology may provide means of reproducing superior genetic versions of production animals. Licensing of this technology is now under way.

The Air Force Research Laboratory (AFRL) has successfully utilized Partnership Intermediary Agreements (PIAs) as defined in 15 USC § 3715 to interact and leverage state and local government resources relative to economic development and community outreach. AFRL has four PIAs with the states of New York, Florida, Ohio, and New Mexico and has leveraged over $12 million in state and local government funds and resources for promoting AFRL capabilities providing small business assistance and community outreach. For example, the AFRL PIA with New Mexico has supported the development of over 50 small-business

EPSCoT has the flexibility to support cooperative initiatives between technology developers and local entities concerned with the diffusion and application of new technologies.

CRADAs, provided technical assistance to over 150 SBIR awardees in New Mexico, as well as supported the development of 53 CRADAs and Educational Partnership Agreements with universities, community colleges, and public school districts in New Mexico. The Air Force recognized the importance of these activities by granting them the General Ronald Yates Technology Transfer Team Award for 1997.

A different approach to collaboration with the states is exemplified by the Department of Commerce's EPSCoT initiative (Experimental Program to Stimulate Competitive Technology). This program was established in 1998 to support state and local efforts to promote technology-based economic development. As such, EPSCoT has the flexibility to support cooperative initiatives between technology developers and local entities concerned with the diffusion and application of new technologies. Eligibility to apply for EPSCoT grants is restricted to "those states that have historically received less Federal R&D funds than a majority of the states."[39] In 1999, eligible states were those that ranked lower than 26th in the distribution of Federal R&D funds between 1990 and 1996. The program has had limited resources, however, awarding $2 million in FY 1999. An evaluation program is currently under way to assess the role the program has played in facilitating technology-based economic development.

Although economic development has been a productive area for partnerships among the laboratories and state and local governments, transferring federal laboratory technologies to the states for their own use has been less successful. Few state officials view federal laboratories as sources of technology for their use and laboratories seldom pursue opportunities to meet state and local government internal technology needs. Even where such partnerships may be proposed, differing contracting practices among the states may pose obstacles to cooperation. Boilerplate terms for state contracting are often at odds with federal technology transfer laws and practices, and the intellectual property rights sought by the states are reminiscent of those sought by the federal government prior to the Bayh-Dole Act and Executive Order 12591. For example, the states often seek to own laboratory inventions and project data arising from cooperative work and want the laboratories to commit to firm deliverables rather than "best efforts." The states sometimes

[39] 15 USC § 3704(f))

require indemnification from the federal laboratories against any liability and may defer payments to the laboratories for work to be performed. These terms are generally nonnegotiable.

The states and the federal laboratories have begun to find innovative ways to cooperate to further economic development, using federal technology resources, although they have not pursued partnering through CRADAs to meet state government technical needs. The latter situation might best be addressed by a greater understanding on both sides of the potential benefits of such partnerships. In addition, the prospect of such arrangements would be furthered by state adoption of laws similar to the Bayh-Dole and Stevenson-Wydler Acts, thus providing complementary approaches at the state and federal levels on technology transfer and intellectual property practices. Enactment of these types of laws might also invigorate the states' ability to work with their own universities both to meet their own technology-based needs and to support economic development.

Chapter 4: What Constitutes Success in Technology Transfer?

The question of how to measure the success of federal technology transfer efforts under both the Stevenson-Wydler and Bayh-Dole Acts has occupied the attention of the agencies, the business community, interested members of Congress, and academic observers. Answering this question requires an understanding of what results Congress sought to achieve by authorizing these programs. The legislation suggests that Congress' ultimate objectives were to improve the competitiveness of American industry by the introduction of new technologies, generate new economic activity and new jobs within these industries, and strengthen the scientific and technical capabilities of the federal laboratories and their ability to partner with U.S. industry. To accomplish these ultimate objectives, the laws focused on a number of things that needed to be done, e.g., making technology transfer an important mission of the federal laboratories, creating a simple form of agreement for laboratories to use in partnering with industry, and defining the criteria to be used in selecting research partners or licensees for agency intellectual property.

Like most research-based activities, technology transfer produces its ultimate results on a time scale much longer than the budgetary cycles of the federal government. The exact consequences of these programs for industrial competitiveness and their effect on industrial economic activity are not easily measured, especially in the first years following their enactment. However, it has been possible to measure agency progress toward the intermediate goals set by the legislation. In the first few years following passage of the CRADA authority, laboratories celebrated the signing of each CRADA and measured their success by the number of CRADAs they had with the private sector. As time passed and it became possible to identify specific outputs from these activities, especially intellectual property, the focus of attention shifted to those outputs. The laboratories and agencies counted invention disclosures, patent applications, the number of licenses and, as time passed, the amount of royalty income received. In addition, scholars and others observing the agency and laboratory activities attempted to measure other, more subjective levels of activity and outputs needed to produce the economic outcomes ultimately desired by Congress.[40]

Technology transfer produces its ultimate results on a time scale much longer than the budgetary cycles of the federal government.

[40] For example, see *Crow & Bozeman, Limited by Design: R&D Laboratories in the U.S. National Innovation System,* 1998. The Association of University Technology Managers (AUTM) has faced a similar challenge in attempting to assess the results of university intellectual property management under the Bayh-Dole Act. It has begun to collect and report data from member

These activities and outputs have been measured through relatively objective data elements and have provided an adequate basis to assess the initial implementation of the programs authorized by Congress. However, with the passage of time and the increasing emphasis placed on performance measures for government programs, there is a clear need for better measures of the outputs under the laws and, as experience accumulates, of progress toward the ultimate outcomes desired by Congress. As we suggested in our last report, we need to "continue to develop systems to measure program outputs, including the immediate effects of the agency actions on private sector partners, as well as information concerning the longer term and broader economic effects of the activity."[41] In working toward such measures, the goal is not simply to demonstrate to Congress the success of technology transfer in improving the competitiveness of the nation, but also to provide the agencies and laboratories with the tools to manage their resources toward the achievement of the statutory objectives.

As a first step in the process of developing such a measurement system, we wish to suggest some intermediate goals that the agencies and laboratories should aim for. We believe the achievement of these goals would represent significant progress toward achieving the improved industrial competitiveness envisioned by Congress. In connection with each goal, we list the specific activities that the agencies and laboratories need to engage in to achieve the goals. The five goals presented here are based on the challenges to effective agency/industry partnering identified in this report.

Goal 1. Federal laboratories should systematically manage their intellectual resources and nurture their knowledge base.

Supporting Activities

- Laboratories should require first-line technical managers and supervisors to undergo training in intellectual resource management and to complete annual "refresher" courses.

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universities and colleges that provide at least some estimates of the outputs and outcomes being realized. From the data collected from licensees on earned royalties, they estimate projected gross sales of their licensees and use that number to estimate the number of jobs that such revenues are likely to represent within the industry sectors being served by the licensees. See, *AUTM Licensing Survey FY 1998* at http://www.autm.net/ publications/ survey/index.html

[41] Technology Administration, Effective Partnering, p. 76 (Washington, DC 1996).

- Laboratory R&D projects should be assessed at least annually to determine if such projects have potential commercial benefits.

- Technology advances, characterized as innovations and/or inventions, should be formally identified, documented, and reported, and nondisclosing abstracts should be made available on an open network.

- Technology advances should be periodically reviewed and assessed as to the appropriate disposition and application of the information. Such application may be to publish, protect under domestic and/or foreign patent laws, hold as having commercial potential, or make available for release to the public.

- In judging employee performance and deciding on promotions, agencies and laboratories should recognize the contributions of scientists, engineers, and technology transfer staff members to the development, processing, and application of innovations and inventions.

Goal 2. Decision makers in the public and private sectors can quickly, conveniently, and cost-effectively identify which federal laboratories have the intellectual resources, competencies, and capabilities to help solve specific, critical, technology-based problems.

Supporting Activities

- The agencies, their laboratories, and the FLC should work together to develop a government-wide, user-friendly management information system for federal technology transfer.

- The system (1) reports technical advances at laboratories; (2) describes projects having potential commercial applications; (3) identifies intellectual properties available for licensing; and (4) identifies unique laboratory facilities and capabilities available for use by other federal agencies, state and local governments, and the private sector.

- The system should be linked to other databases, such as the patent records maintained by the U.S. Patent and Trademark office, and to information maintained by individual agencies and laboratories.

Goal 3. Industry, academia, and the federal agencies and laboratories should continue to identify barriers to close collaboration and minimize or eliminate such barriers to better ally with one other to solve technology-based problems that impede progress for a company, an industry, the nation, or mankind.

Supporting Activities

- Representatives of the agencies, the laboratories, and the business community should regularly review CRADA and licensing terms and conditions that cause difficulties in negotiations. These reviews will define industries' needs and relevant government policies. On this basis, contract terms can be revised or policies are clarified, and the material can be made available to the agencies and laboratories for use. (Issues relating to U.S. competitiveness, product liability and indemnification, and intellectual property rights have been identified in this report as requiring this type of
review.)

- Agencies should recognize that a variety of partnership opportunities may be addressed through a CRADA and that the terms of the agreement must be appropriate to the specific opportunity. The agencies and laboratories, in collaboration with business representatives, have a range of CRADA terms to meet these differing situations. The laboratories and their private sector partners are able to apply the most appropriate terms to expedite the initiation of projects to meet the needs and interests of the respective parties.

Goal 4. The federal government should develop the processes to monitor continuously the technology transfer performance of the federal agencies and laboratories and to identify areas in which performance could be improved. Once such areas for improvement are identified, the necessary resources should be applied to help implement the desired improvements.

Supporting Activities

- The Interagency Working Group on Technology Transfer (IWG/TT), together with its member agencies and the FLC, should facilitate the convening of workshops where federal technology transfer professionals come together with industry representatives to develop and adopt a common set of principles and practices to guide the laboratories in their technology transfer

activities with one another, universities, state and local governments, and the private sector.

- The IWG/TT and its member agencies should work in cooperation with representatives of state governments to develop policies that enable closer interactions and cooperation between the states and the federal labs to support technology-based initiatives of importance to states and their local governments.

- The FLC (and other interested public or private entities) should establish enhanced or new professional training courses for use by labs, either individually or in groups. The training addresses such diverse issues as export control regulations, international technology transfer, knowledge and intellectual resource management, negotiating skills, utilization of an integrated Technology Transfer Management Information System, and how best to assist local communities in developing jobs and infrastructure. Particular emphasis is given to the training of first-line technical managers and supervisors on intellectual resource management.

Goal 5. The agencies and laboratories should agree to a system of output and outcome measurements based on the goals stated here.

Supporting Activities

- Through discussions among the member agencies of the IWG/TT, the foregoing goals should be reviewed, revised as necessary, and adopted to guide the management of federal technology transfer programs.

- The agencies should review, revise, and adopt lists of necessary supporting activities for the goals and use those lists as a basis for setting their own performance objectives.

- The agencies should monitor their progress in carrying out the activities and accomplishing the goals.

The goals presented in this section, along with the suggested supporting activities, are not the ultimate outcomes sought by Congress in adopting the technology transfer legislation. Achieving these goals will not guarantee that an improvement in industrial competitiveness has been achieved through federal technology transfer. But we believe the goals

are the next steps the agencies need to take in working toward that outcome. If the agencies can achieve these goals across the federal laboratory system, they will not only have addressed the issues identified in this report but will have made important progress toward the outcome of enhanced technological competitiveness.

We hope that these goals generate debate among the agencies, the business community, and legislators concerning the goals to be pursued. Once goals are set, road maps of supporting activities can be developed to help the agencies get there. From this exercise, meaningful measures of performance can be defined that will provide a basis for assessing the progress of the federal technology transfer programs. The Department of Commerce is committed to working with the agencies through the IWG/TT to carry out this plan.

Appendix A: Implementing the Stevenson-Wydler Act at the Federal Laboratories: Diversity Is the Norm

This Appendix discusses the missions of the principal agencies involved in research and development (R&D) and discusses the ways in which the authorities of the Stevenson-Wydler and Bayh-Dole Acts have been implemented by the agencies within the context of those missions. A brief description of the activities of the agencies under these authorities is also provided.

Department of Agriculture

The Department of Agriculture has been transferring technology to the nation's agricultural community since its creation in 1860. The establishment of the land-grant colleges and universities by the Morrill Act of 1862 laid the foundation for agricultural productivity with its emphasis on teaching, research, and extension services. During the remainder of the nineteenth century and much of the twentieth, agriculture was the principal focus for federal R&D programs. Even today it is an important science- and technology-based sector of our national economy.

Today the Department of Agriculture, through its many component organizations, is dedicated to enhancing the quality of life for the American people by supporting production of agriculture, including ensuring a food supply, caring for the lands, and supporting sound rural development. As part of that mission, the Department supports agricultural research at its own laboratories and at external research organizations, including universities. In fiscal year (FY) 1998, the Department had an R&D budget of approximately $1.44 billion. The Agricultural Research Service (ARS) received $757.9 million, largely for intramural research programs. The Forest Service received $187.8 million, most of which went for intramural research. The Cooperative State Research, Education and Extension Service, the principal liaison with the university community, received $386.4 million, $366.5 million of which went to universities and colleges.

The principal intramural research organization within the Department is the ARS, which is charged with extending scientific knowledge in a broad range of programs. The agency's research work at present focuses on three categories: animal production, natural resources, and crop

production. These national research programs are developed in consultation with the agricultural community and carried out largely within the national research facilities of ARS. The Forest Service conducts research concerning new technologies that can be used to sustain the health, productivity, and diversity of the nation's forest and rangelands. This new knowledge is intended to benefit private landowners in managing their lands as well as to serve the needs of public land managers.

The Cooperative State Research, Education, and Extension Service (CSREES) links the research and education programs of the Department, working with the land grant institutions in each state and many other educational institutions. CSREES seeks to advance research, extension services, and education in food and agricultural sciences, working through partnerships with public and private sector organizations. As part of this work, CSREES sponsors research on agricultural product development, plant and animal genome, integrated pest management, and other topics of concern to the agricultural community. One of its principal efforts is the National Research Initiative Competitive Grants Program, which is charged with funding research on key problems in biological, environmental, physical, and social sciences on a peer-reviewed competitive basis.

The Department's long history of technology transfer in support of agriculture has given it an opportunity to develop and refine an approach that suits its mission and the social and economic context in which it operates. The Department recognizes that, in many circumstances, the results of its research are best disseminated through publication. As a result, the Department contributes nearly 9,000 publications per year to the world's knowledge base. In some situations, however, patent protection is sought for the innovations produced in its research programs. The Department decides whether to pursue patenting or other legal protection for its inventions by determining whether transfer to the private sector for development is necessary "as an intermediate step in getting the benefits to the ultimate users, farmers and consumers."[42]

In implementing the Stevenson-Wydler and Bayh-Dole Acts, the Department of Agriculture has created separate offices of technology transfer to represent its two principal intramural research organizations-the ARS and the Forest Service. Researchers within the ARS are served by the ARS Office of Technology Transfer (OTT), headquartered in Washington. Authority to enter into Cooperative Research and Development Agreements (CRADAs) on behalf of ARS and to license its patents has been

[42] Agricultural Research Service, *Technology Transfer in ARS,* p. 1.

delegated to OTT. Its staff includes technology transfer coordinators located in six geographical areas across the country, who work with ARS scientists to transfer technology. The ARS was the first federal laboratory to sign a CRADA and has executed a cumulative total of 833 CRADAs through the end of FY 1998.

In the Forest Service, authority to enter CRADAs has been delegated to the Director of the Forest Products Laboratory and the directors of various field operations and experimental stations maintained by the Forest Service. License agreements are negotiated and administered by the Office of the Forest Service Patent Advisor at the Forest Products Laboratory in Madison, Wisconsin. For FY 1998, the combined technology transfer staffs of the Department of Agriculture received 208 new invention disclosures, had 67 patents issued, received $2,415,000 from invention licensing, and entered into 98 new CRADAs.

Department of Commerce

The Department of Commerce works in partnership with business, universities, communities, and workers to promote U.S. competitiveness by strengthening economic infrastructure, by providing cutting-edge science and technology and an information base, and by managing national resources. The Department conducts research in support of several parts of its broad mission, receiving $948.6 million in R&D funding in FY 1998.

The National Institute of Standards and Technology (NIST) received approximately $394.4 million in research and development funding, with $226 million used for its intramural research work. NIST is unique among federal research facilities in having the mission of promoting economic growth by working directly with industry to develop technology, measurements, and standards. It does this work through four interrelated programs: the Measurement and Standards Laboratories, the Advanced Technology Program, the Manufacturing Extension Partnership, and the National Quality Program. The Measurements and Standards Laboratories provide technical leadership in a wide variety of scientific, technical, and engineering fields. The Advanced Technology Program provides cost-shared funding to industry for high-risk R&D projects, and the Manufacturing Extension Partnership supports a nationwide network of locally managed extension centers offering technical assistance to the nation's smaller manufacturers.

OFFICE OF TECHNOLOGY POLICY

The National Oceanic and Atmospheric Administration (NOAA) received more than $519 million in R&D funding in FY 1998 to support its two-fold mission of environmental assessment and prediction and environmental stewardship. Intramural research programs received $432 million of this funding. NOAA's research programs are carried out by five major divisions and numerous special program units. The divisions include the National Weather Service, the Office of Oceanic and Atmospheric Research, the National Environmental Satellite, Data and Information Service, the National Ocean Service, and the National Marine Fisheries Service. NOAA's broad responsibilities are supported by a program of research conducted primarily at NOAA laboratories, with additional research supported at universities throughout the country. This research work is focused on three main areas: tracking and warning of dangerous weather systems; helping to guide the nation's use and protection of ocean and coastal resources; and improving our understanding of the oceans and atmosphere that sustain life on the planet.

Research funding also went to the National Telecommunications and Information Administration (NTIA) and to the Bureau of the Census. NTIA received $25.5 million in R&D funding to support its mission as principal adviser on telecommunications policies affecting economic and technological advancement and telecommunications regulation. Some of this research is carried out by the Institute for Telecommunication Sciences (ITS), the principal federal laboratory for telecommunications science and engineering. ITS also provides specific telecommunications planning and evaluation for federal agencies and U.S. industry.

The Bureau of Census, a part of the Economics and Statistics Administration, received $8.6 million in funding for its economic and social science research. Census conducts most surveys for the executive branch, using its business surveys as a basis for its periodic economic indicators and also conducting the decennial census.

Each of these Commerce agencies is involved in technology transfer activities of various kinds. Because of its mission of direct involvement with industry, NIST is engaged in most of the agency's industry/laboratory partnerships. Many of these partnerships are with consortia of companies in specific sectors, seeking to explore an infrastructural issue of common interest to the sector. In such consortia, the emphasis is generally on a broad dissemination of research results within the sector, rather than the creation of intellectual property and its licensing.

The Department of Commerce has delegated authority to negotiate and execute CRADAs and licenses to each of the organizations conducting research. NIST has delegated that authority to each of its Measurements and Standards laboratories while maintaining a central Office of Research and Technology Applications (ORTA) at its principal facility in Gaithersburg, Maryland. Patent licensing at NIST is handled by the central ORTA. NOAA, which has laboratories throughout the United States, also delegates authority to enter into CRADAs to its individual laboratories, while maintaining its primary ORTA in Silver Spring, Maryland. This ORTA handles patent licensing for NOAA with the Office of General Counsel. ITS, the NTIA laboratory, has an ORTA but also coordinates with a common ORTA in Boulder, Colorado, with NIST and NOAA research facilities located there. ITS has been delegated authority to enter into CRADAs and patent licenses. For FY 1998, Commerce's research organizations received 40 invention disclosures, had 19 patents issued, received $240,000 from invention licenses, and entered into 77 new CRADAs.

Department of Defense

The Department of Defense (DoD) has the largest R&D budget of all agencies (more than $34 billion in FY 1998) but the bulk of that funding (more than $30 billion) is allocated to developmental work. DoD research totaled approximately $3.9 billion in FY 1998, substantially less than the research funding received by the Department of Health and Human Services (HHS) or the National Aeronautics and Space Administration (NASA).

A new paradigm for technology partnering with the private sector is emerging at DoD as a result of current budgetary and technological trends. The Department recognizes that the huge increases in private sector research expenditures, both in the United States and around the globe, have made it extremely difficult for it to stay on the cutting edge of all of the technologies important to it. The new paradigm puts an emphasis on partnering with the private sector, other agencies, and academia to leverage the Department's position in militarily critical technologies.

As a result of these developments, DoD has committed itself to technology transfer of several sorts. Its technology transfer programs include cost sharing of its research with the private sector (dual use technologies), integrating advanced commercial technologies into its work (spin-on technologies), and making existing technologies more affordable

through spin-offs to the private sector. These methods of technology transfer have been adopted as a basic part of DoD policy and are being implemented throughout the DoD research system.[43]

DoD's technology transfer program is decentralized, with more than 100 ORTAs and other technology transfer focal points within its large and complex laboratory system. At the same time, the Department recognizes its need to coordinate these and related activities and has created the Office of Technology Transition in the Office of the Secretary of Defense, pursuant to 10 USC § 2515, to meet this need. The office provides leadership within DoD on technology transfer programs under the Stevenson-Wydler and Bayh-Dole Acts. It also manages related technology partnership programs, such as the Dual Use Science and Technology Program, the SBIR Program, the Manufacturing Technology Program (ManTech), portions of the information collection and dissemination activities of the Defense Technical Information Center, the Independent Research and Development program, the Title III program under the Defense Production Act, and the Commercial Operations and Support Savings Initiative.

The three service branches of DOD, the Army, Navy, and Air Force, maintain laboratories with a wide range of state-of-the-art human and physical resources. These resources include expertise in a number of technical areas as well as world-class facilities and equipment, many of which are unique. DOD differs from all of the other federal agencies in that it has mission-related responsibilities that are equivalent to activities at practically all of the other agencies and their laboratories. These responsibilities include space missions, medical research, land management, health care, telecommunications, weaponry, national security, transportation, environmental management, and training.

The Army has delegated authority to enter into CRADAs and patent license agreements to the commanders and directors of its laboratories, R&D centers, test and evaluation centers, and medical institutes. Each of these organizations has an ORTA that is the point of contact for potential users of a laboratory's technology infrastructure. The Army's Domestic Technology Transfer Program is intended to work through the decentralized, coordinated efforts of these ORTAs.

[43] DoD, Directive 5535.8 (DoD Technology Transfer (T2) Program), May 14, 1999; DoD, Directive 5535.3 (DoD Domestic Technology Transfer (T2) Program), May 21, 1999.

For the Navy, signature authority for standard CRADAs and licenses has been delegated to all major Navy facilities where R&D is done. However, only slightly more than half of those facilities have formally established ORTAs. For management and control purposes, the collection of licensing fees and the distribution of royalties are performed at the Office of Naval Research headquarters.

The Air Force has authorized commanders and directors of each of its research, development, test, and evaluation centers to enter into CRADAs and licensing agreements. It maintains 28 ORTA offices, with others at each of its ten directorates and at other Air Force research centers.

DoD's OTT recently conducted a review of certain of the Department's CRADA activities to assess the benefits flowing from these agreements. The study evaluated a sampling of CRADAs against the Department's guiding management principles for its space and technology program[44] and found that the agreements satisfied these principles in a variety of ways. The study produced a number of interesting findings. For example, the CRADAs, rather than leading directly to commercial products, typically "entail knowledge-share opportunities that facilitate advances in research that lead to product or process improvements." In addition, there was broad acceptance of the CRADAs by the laboratories as "mission extenders" that helped the laboratories to meet their technological needs by investigating commercial technologies to meet government needs. A particular example was a CRADA between the Walter Reed Army Institute of Research and the Medical Technology and Practice Patterns Institute, Inc., relating to a transdermal vaccine delivery system. The CRADA "provided a means for ideas that would have otherwise been held captive in financially strapped laboratories to flourish in the commercial sector where there is interest and scientists available and ready to apply the technology."

[44] These principles are (1) Transition Technology to Address Warfighting Needs; (2) Reduce Cost; (3) Strengthen the Industrial Base; (4) Promote Basic Research and (5) Assure Quality. DoD, Cooperative R&D Agreements: Value Added to the Mission, April 1999, at http://www.dtic.mil/techtransit

In addition, the DoD continues its traditional involvement with local governments and the communities in which their bases and laboratories are located. The DoD laboratories also have an almost unique practice among the federal laboratories through their formal partnering with universities under CRADAs. In 1995, they entered into 65 CRADAs with universities while all of the other federal agencies and their laboratories had a combined total of 10 CRADAs with universities.

For FY 1998, the DoD received 1028 invention disclosures, had 579 patents issued, received $1,560,000 from invention licensing, and entered into 399 new CRADAs. (For a breakdown of these numbers by Service branch, see Appendix C.) In looking at these data, it is important to recognize that DoD and its laboratories, like NASA and the Department of Energy, have a long history of obtaining "defensive" patent protection to ensure that patents obtained by others would not block its access to militarily important technologies. As a result, the quantitative metrics presented in this report show a disproportionately large number of patents in relation to the number of licenses that the services grant each year.

Department of Energy

The Department of Energy (DOE) is the science and technology agency whose research supports our nation's energy security, national security, and environmental quality and contributes to a better quality of life. The Department traces its origins to the Manhattan Project and the national effort to develop an atomic bomb during World War II. Following the war, Congress passed the Atomic Energy Act of 1946 that created the Atomic Energy Commission (AEC) to take over the scientific and industrial complex related to work with nuclear energy. The AEC initially focused on national security-related uses of atomic energy but the Atomic Energy Act of 1954 gave birth to a commercial nuclear power industry and gave the AEC regulatory authority over it. In 1974, the AEC was abolished and two new agencies created—the Nuclear Regulatory Agency to regulate the commercial nuclear power industry and the Energy Research and Development Administration to manage the national-security-related programs.

In response to the challenges presented by the energy crisis of the 1970s, the DOE was created to provide a unified federal approach to energy issues. The new Department undertook responsibility for long-term, high-risk research and development in energy technology, federal power

marketing, energy conservation, nuclear weapons, and energy regulation. During the 1970s the Department emphasized energy development and regulation and in the 1980s shifted to an emphasis on nuclear weapons research, development, and production. Since the end of the Cold War, the Department has focused on environmental cleanup of the nuclear weapons complex, nonproliferation and stewardship of the nuclear stockpile, energy efficiency and conservation, technology transfer, and industrial competitiveness.

The Department engages in a wide range of technology partnerships with others as a part of its mission. Many of these partnerships are integral parts of DOE programs. For example, the Office of Industrial Technologies (OIT), one of the components of the Office of Energy Efficiency and Renewable Energy, creates partnerships among industry, trade groups, government agencies, and other organizations to research, develop, and deliver advanced energy efficiency, renewable energy, and pollution prevention technologies for industrial customers. Through its "Industries of the Future" program, OIT creates partnerships between industry, government, and supporting laboratories and institutions to accelerate technology research, development, and deployment. The strategy is being implemented in nine energy- and waste-intensive industries, each of which produces a document outlining its vision for the future, and a technology roadmap to identify the technologies that will be needed to reach those goals. OIT then works with the Department's laboratories to respond to the research needs by streamlining industries' access to the expertise and capabilities of the laboratories.

Similarly, the Office of Building Technology, State and Community Programs (BTS) is facilitating an industry-led initiative to develop technology roadmaps focusing on various aspects of the building industry. Roadmapping provides a framework for cooperative technology development efforts and market transformation activities that will help to accelerate the adoption of new technologies and approaches in the marketplace. It also helps to align government R&D resources with the high-priority needs identified by industry.

The Office of Environmental Management (EM) within the Department manages the largest environmental management program in the country—the cleanup of legacy wastes from nuclear weapons manufacturing. EM provides science and technology, ranging from basic research to technology development and demonstration, including deployment of innovative remediation technologies. Technical assistance is provided to successfully deploy innovative scientific and technological solutions to

clean up the sites, while addressing long-term environmental stewardship needs.

From EM's investment in innovative remediation technology, some 220 new environmental remediation technologies are now available from industry to address DOE, other federal agency, private sector, and global environmental cleanup challenges. Within DOE, deployments of innovative remediation technologies have occurred at 10 sites, located in 10 states. Of those 220 remediation technologies, 160 have been deployed at least once (73 percent), of which 67 (42 percent) have been used multiple times, across multiple sites, or have become baseline cleanup methods. EM's accelerated deployment work has resulted in nearly 100 technology deployments that could yield over $1.5 billion in cost savings. The environmental management industry is actively participating in developing technologies for cleanup of DOE's contaminated sites. Over 75 private sector technology development firms from 31 states have participated, more than two-thirds of which are small businesses.

In addition to these kinds of programmatic partnerships, the Department supports technology transfer partnerships with the private sector built on the capabilities and expertise of its laboratories and facilities. These technology transfer partnerships use a variety of mechanisms, including CRADAs and the licensing of intellectual property.[45] The DOE has unique statutory authority under which it conducts these technology transfer

[45] The Department has identified the following mechanisms for achieving technology transfer in this manner: (1) Cooperative Agreements (generally cost-shared with industry, universities, or others); (2) Cost-Shared Contracts/Subcontracts (procurement-based collaborations for mutual benefit); (3) Personnel Exchange Programs (allowing government or laboratory staff to work in industry facilities or industry personnel to work in government labs); (4) R&D Consortia (arrangements involving multiple federal and nonfederal parties working for a common R&D objective); (5) Technical Assistance to Small Business (undertaken in response to an inquiry from an individual or organization seeking to further knowledge, solve a specific problem, or improve a process or product). DOE R&D Council Technology Transfer Working Group, Partnering for Success: A Review of DOE Technology Transfer Policies and Procedures (June 1999), App. A, available at http://www.er.doe.gov/production/octr/aeptr/ttwg.htm

activities. Under the Atomic Energy Act of 1954, the DOE was granted authority to take title to all inventions made in the United States useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon. DOE may also take title to all inventions useful in the production or utilization of special nuclear material or atomic energy, made or conceived under contracts or arrangements entered into for the benefit of DOE, whether or not funds are expended.[46] At the same time, under that Act, DOE was directed to establish a program for the dissemination of scientific and technical information produced at its laboratories for the advancement of science and industry. Thus the agency and its laboratories have had dual roles—identifying and protecting sensitive or classified information for the security of the nation while sharing its other information with the public.

Unlike most other federal agencies, DOE carries out most of its mission activities through a system of federal laboratories at government-owned, contractor-operated (GOCO) facilities. These laboratories, referred to as National Laboratories, are typically operated under 5-year, management and operating contracts by universities, not-for-profit organizations, and large businesses. This operating structure dates back to the 1940s when the decision was made to keep the nuclear weapon laboratories separate from the Defense Department, and to retain a workforce of nonfederal employees.

The unique statutory authorities and the use of GOCO laboratories introduce additional legal complexities into the Department's technology transfer efforts. DOE has, through its management and operating contracts, waived intellectual property rights to the inventions of its contractor-operators under terms that parallel those found in the Bayh-Dole and Stevenson-Wydler acts. Since laboratory employees are not federal employees, the GOCO operators may, with prior DOE approval, assert their rights in copyrightable works, as well as patentable inventions, for purposes of licensing for commercialization. In addition, under the National Competitiveness Technology Transfer Act of 1990, Congress granted the DOE the authority to delegate to their laboratories the authority to enter into CRADAs.

As a result of their advanced national security work, the DOE national laboratories and its production facilities have developed unique competencies and capabilities that often exceed those found in the private sector or in other laboratories. For example, as a part of their nuclear

[46] 42 USC §§ 2168, 2181-2183.

weapons work, these laboratories pushed the domestic industry to develop ever faster, more powerful computers and compatible information storage and telecommunications systems.

The approach to intellectual resources varies widely across the breadth of the DOE laboratory system. Its weapons laboratories and production facilities have a history of conducting R&D and protecting the results for mission purposes. However, the DOE laboratories performing research in environmental quality and energy efficiency and conservation have a strong charge to share the results of the work with the public. These differences in mission can lead to differences in approach to the use of patenting, CRADAs, and patent licenses.

The DOE has delegated CRADA authority to its two government-owned, government-operated (GOGO) fossil fuel laboratories and each of its GOCO laboratories. Management of the technology transfer process for DOE has been delegated to the Department's field offices, which now have authority to approve most CRADAs. Licensing practices at the DOE contractor operated laboratories are similar to those followed by universities under the Bayh-Dole Act.

DOE recently conducted a review of its technology transfer activities designed to "review, evaluate and recommend improvements to DOE's technology transfer programs conducted by the management and operating (M&O) contractors at DOE's national laboratories, and the oversight of such programs by DOE field and headquarters."[47] The report noted that DOE and its labs had learned a great deal about effective technology transfer in the 10 years since the DOE laboratories had been authorized to establish technology transfer as a mission at its GOCO laboratories. While challenges remained, "the challenges are more about how to bring greater consistency across the complex in what is offered to DOE's partners, how to represent the program results to constituencies, and how to manage a very large portfolio of relationships between laboratories and non-federal parties in an increasingly global economy."

The report made several important observations concerning management and oversight of the technology transfer program. First, it noted that DOE had no senior-level point of contact at DOE headquarters "for program offices to turn to on technology transfer issues for help in

[47] DOE R&D Council Technology Transfer Working Group, Partnering for Success: A Review of DOE Technology Transfer Policies and Procedures (June 1999), App. A, available at http://www.er.doe.gov/production/octr/aeptr/ttwg.htm

reconciling problems, raising issues to a higher level or for coordinating Administration or Departmental positions during discussions with other federal agencies or Congress." To remedy this problem, the group recommended the creation of a leadership position at DOE headquarters for technology transfer issues. Shortly after issuance of this report, Secretary of Energy Richardson announced the appointment of a senior advisor for technology policy to serve as the focal point for the Secretary's involvement in technology transfer. The report also recommended a series of improvements in the technology transfer programs, including improved accessibility to partnership opportunities, optimization of the CRADA negotiation and approval process, and the development and implementation of a system of performance and effectiveness measures.[48]

For FY 1998, the DOE received 1313 invention disclosures, and DOE's laboratories had 512 patents issued, received $10,536,000 from licensing, and entered into 266 new CRADAs.

Environmental Protection Agency

The Environmental Protection Agency (EPA) is the principal federal agency responsible for monitoring and regulating environmental quality. Its mission is to protect human health and to safeguard the natural environment, air, water, and land, upon which life depends. In support of this broad mission and related regulatory authority, EPA conducts research and development in relevant areas of science and technology through its own system of laboratories and through the sponsoring of external research by industry, universities and other research performers. In FY 1998, EPA received $571.2 million in total research and development funding, with $255 million expended on intramural research. Environmental research is critical for developing the scientific understanding and the technological tools to allow the nation to enhance environmental quality for current and future generations. This investment will provide a scientific basis for developing cost-effective environmental policies, create the knowledge base for citizens to make wise

[48] The other recommendations were to (1) Clarify, update and disseminate DOE technology transfer policies and guidelines to ensure appropriate consistency and uniformity across the DOE complex; (2) Promote the effectiveness of ombuds capability at each R&D laboratory to assist industry with issue resolution; (3) Encourage the use of sufficient resources and incentives to adequately and appropriately stimulate technology partnerships; and (4) Minimize the likelihood and perception of DOE laboratories competing with the private sector.

environmental decisions, and enable new and better approaches to environmental protection.

ORD maintains a number of research facilities around the country, including the National Center for Environmental Assessment, the National Exposure Research Laboratory, the National Health & Environmental Effects Research Laboratory, and the National Risk Management Research Laboratory. In addition to the ORD activities, research is also conducted by the Office of Air and Radiation; Office of Water; Office of Prevention, Pesticides, and Toxic Substances; and Office of Solid Waste and Emergency Response. The work is done pursuant to a series of research strategies and plans covering important environmental issues. At present, the strategies relate to ecological research, environmental monitoring and assessment, global change, particulate matter, pollution prevention, and waste research.

EPA's research programs cover a wide spectrum of environmental sciences and engineering disciplines consistent with its broad regulatory authority. EPA has a strong commitment to share that research with industry and the public to improve human health and the environment. With the authority granted in the Federal Technology Transfer Act, EPA actively shares its expertise and knowledge through several technology transfer mechanisms including Cooperative Research and Development Agreements (CRADAs), collegial interchanges, and the licensing of intellectual property.

Through an innovative cooperative agreement with the Battelle Memorial Institute, the EPA established the Environmental Technology Commercialization Center (ETC^2) to facilitate the transfer of EPA technologies and capabilities to industry, particularly small business. ETC^2 is a network of technology professionals dedicated to interact with EPA researchers to facilitate technology transfer initiatives and foster interaction with state agencies, industry associations, and other stakeholders. The Coordinator of the Federal Technology Transfer Act for EPA, located at the ORD research facility in Cincinnati, Ohio, is responsible for this initiative along with the other technology transfer mechanisms. For FY1998, the EPA received 14 invention disclosures, had one patent issued, received $100,000 from invention licensing, and entered into 12 new CRADAs. For FY 1999, the EPA received 5 invention disclosures, had 5 patents issued, received $100,000 from invention licensing, and entered into 14 new CRADAs, receiving $114,000 and $1,044,500 in cash and in-kind contributions respectively from CRADA partners.

Department of Health and Human Services

The Department of Health and Human Services (HHS) is the principal agency for protecting the health of Americans and providing essential human services. HHS carries out this mission through more than 300 programs in such areas as medical and social science research, preventing the outbreak of infectious disease, ensuring food and drug safety, managing the Medicare and Medicaid health insurance programs, running the Head Start program, and managing many other programs for low-income families, children, and older Americans. Many of its programs are delivered through state and local government agencies and private sector grantees. HHS is also the federal government's largest grant-making agency and operates the nation's largest health insurance program.

HHS received $13.7 billion in R&D funding in FY 1998. The largest recipient of funding was the National Institutes of Health (NIH) at $12.9 billion. NIH is the world's premier medical research organization, annually supporting over 35,000 research projects. It includes 25 Institutes and Centers, including 17 separate health institutes, the National Library of Medicine, and the National Human Genome Research Institute. Of the $12.9 billion received by NIH, $2.4 billion supported the intramural research programs of the Institutes and the balance went to other research performers, principally universities and other nonprofit institutions.

The Centers for Disease Control and Prevention (CDC) received $343.6 million in R&D funding in FY 1998. The CDC provides a system of health surveillance to monitor and prevent the outbreak of diseases, maintains national health statistics, provides for immunization services, and guards against international disease transmission. The other principal recipients of HHS research funding were the Food and Drug Administration ($142.9 million), which ensures the safety of foods and cosmetics and the efficacy of drugs and medical devices, and the Agency for Health Care and Policy Research ($146.5 million), which supports cross-cutting research on health care systems, quality, and cost.

The research conducted by NIH and other elements of the Public Health Service (PHS) Operating Divisions of HHS probably has the greatest potential for producing technologies that can be transferred to the private sector for commercialization. A key part of the department's mission is protecting and improving the public health, which is often achieved through the availability of new therapeutic and diagnostic drugs, vac-

cines, therapies, and medical devices brought to market by private sector companies. These new products and services are frequently based at least in part on research work supported by PHS, and a transfer of technology from these agencies often plays a critical role in bringing about this result. The transfer may take the form of a biological sample provided under a Material Transfer Agreement, a license to an invention made by a HHS researcher, a CRADA in an area of mutual interest, or the authoring of a technical paper for publication. As a result of the close coupling between the department's research and these dynamic industries, in FY 1998 PHS agencies accounted for nearly 70 percent of the royalty income from all of the federal agencies.

The PHS agencies have articulated their approach to technology transfer in several policy documents. These documents describe the agencies' approach to patenting of new technologies emerging from their research, to the licensing of those technologies, and to the establishment of CRADAs.[49] In explaining the circumstances in which a patent will be sought, PHS policy states:

> PHS generally seeks to patent and license biomedical technologies when a patent will facilitate and attract investment by commercial partners for further research and commercial development of the technology. This is critical where the utility of the patentable subject matter is as a potential preventive, diagnostic, or therapeutic product. However, it also could occur when a patent is necessary to encourage a commercial partner to keep important materials or products available for research use.[50]

The policy notes that in many circumstances patent protection will not be sought:

> Patent protection is generally not sought by PHS where further research and development is not necessary to realize the technology's primary use and future therapeutic, diagnostic, or preventive uses are not reasonably anticipated. For example, PHS will generally not seek patent protection for research tools, such as transgenic mice, receptors, or cell lines. For research tools, the public interest is served primarily by ensuring that the tool is widely available to both academic and commercial scientists to advance further scientific discovery. Secondarily, a financial return to the

[49] U.S. Public Health Service, Technology Transfer Manual, Ch. 200, PHS Patent Policy; Ch. 300, PHS Licensing Policy; Ch. 400, PHS CRADA Policy, found at http://www.nih.gov/od/ott

[50] U.S. Public Health Service, Technology Transfer Manual, Ch. 200, PHS Patent Policy, found at http://www.nih.gov/od/ott

> public is obtained through royalties on the research tool that has significant commercial value.
>
> In addition, when commercialization and technology transfer can best be accomplished without patent protection, such protection will not be sought. For example, some technologies may be transferred to the private sector most expeditiously through publication. For such technologies, patenting and licensing are unnecessary and could inhibit broad dissemination and application of the technology. Methods of performing surgical procedures, for example, could fall within this category.

There is also a PHS policy that explains the principles governing the licensing of patented technologies. PHS licenses, rather than assigns, its patents because it allows the agencies to "ensure the broadest and most expeditious development of new products." The agencies' preference for nonexclusive licenses is also explained:

> The agencies prefer to negotiate non-exclusive or co-exclusive licenses whenever possible. This allows more than one company to develop products using a particular technology, products that may ultimately compete with each other in the marketplace. PHS recognizes that companies typically need an exclusive market position to offset the risk, time and expense of developing biomedical diagnostic or therapeutic products; however, companies do not necessarily need to achieve that position by exclusively licensing a government technology used to develop that product. Instead, they frequently are able to add their own proprietary technologies to the technology licensed from the government to ultimately achieve some level of uniqueness and exclusivity for the product.[51]

Additionally, a PHS policy addresses the appropriate use of the CRADA mechanism in the PHS labs. One of the primary concerns expressed relates to the possible effect of the CRADA on the freedom of researchers to discuss and share their ideas. The policy states, "[A] proposed CRADA would not be appropriate if the fundamental mission of the PHS is compromised by creating, either explicitly or indirectly, more than minimal constraints on research freedom and communication." The policy also cautions against excessive reliance on CRADA funding by the laboratories, stating that CRADAs are "not intended to be a general

[51] U.S. Public Health Service, Technology Transfer Manual, Ch. 300, PHS Licensing Policy, found at http://www.nih.gov/od/ott

funding mechanism to support directed research" at the laboratories. The policy also discusses concerns relating to the dissemination of research results, the requirement of an intellectual contribution from the collaborator, the avoidance of conflicts of interest, and the ensuring of fair access to CRADA opportunities.

The authority for entering into CRADAs has been delegated to the heads of the NIH, the CDC, and the Food and Drug Administration (FDA). Within the NIH, Institute and Center Directors have signatory authority to enter into CRADAs; however, all proposed CRADAs must undergo review by the Director of the NIH.

The NIH serves as the lead agency for HHS in the formulation of technology transfer policy and provides patenting and licensing services for NIH, FDA, and other PHS entities through a centralized OTT. Several individual institutes within NIH also have created ORTA offices that provide support to the scientists in their organization and negotiate individual CRADAs. CDC provides the full range of technology transfer services for its own laboratories.

For FY 1998, NIH received 287 invention disclosures, had 171 patents issued, received $39,500,000 from invention licensing, and entered into 43 new CRADAs.

Department of the Interior

The Department of Interior (DOI) mission is to protect and provide access to the nation's natural and cultural heritage and to honor the nation's trust responsibilities to American Indian Tribes. The Department's activities include the management of public lands and of mineral resources on the outer continental shelf, conserve and protect fish and wildlife, preserve the National Park System, and provide reliable, impartial information concerning the earth.

The DOI received approximately $532 million in funding for research and development in 1998. Of this funding, $464.1 million went to the U.S. Geological Survey (USGS), which is responsible for monitoring ground and surface water quality. USGS also provides scientific information related to the environment, natural hazards, mineral, energy, water, and biological resources, as well as serving as the principal civilian mapping agency. The National Park Service received approximately $29.7 million in research funding to support its mission of preserving the national park

system. Funding for research also went to the Minerals Management Service ($29.3 million) to support its mission of managing mineral resources on the outer continental shelf and to the Bureau of Reclamation ($8.8 million) to support its resource management mission and the development of scientific and technical information for more effective management of these resources.

Historically, DOI has worked closely with universities, industry, states, and other departments of the federal government in carrying out its research work. Since 1997 USGS and its scientists have been involved in more than 1100 cooperative water resource projects and 60 national mapping efforts. Within USGS, for example, the Cooperative Research Unit Program has brought state fish and game agencies, universities, and the Wildlife Management Institute together with the Biological Research Division of USGS to conduct research on renewable natural resource questions, as well as participate in education and provide technical assistance. USGS has also sought private sector partners to produce standard geospatial data products, offering a variety of conventional partnership mechanisms. It is now seeking partners to participate in a project to produce a new National Atlas of the United States. The partners are sought to collaborate in market research, software development, and product distribution. The technology transfer emphasis in the past 5 years has spawned a variety of new programs such as National Mapping's Innovative Partnership Program-a cost shared program focusing on technology exchange with universities and nonprofits.

Within the DOI, the four research agencies have delegated authority to enter into CRADAs to their laboratories. In the Bureau of Reclamation, the Denver Colorado Research and Laboratory Services Division has been given this authority. Within the Fish and Wildlife Service, CRADA authority has been given to the 13 Research and Development Centers. In the National Park Service, individual parks are authorized to enter into CRADAs. These organizations are supported by the Department's Solicitor's Office. The largest of the research organizations, USGS is considered one laboratory for purposes of the Act, with its ORTA in Reston, Virginia. That office also oversees a technology maturation program that invests the laboratory's share of royalty income in laboratory projects to advance new technologies and inventions and its technology transfer mission. CRADA and licensing for the remaining DOI Bureaus are coordinated by the DOI Solicitor's Office. For FY 1998, Interior received five invention disclosures, had three patents issued, received $2 million from invention licensing, and entered into seven new CRADAs.

National Aeronautics and Space Administration

NASA was created in 1958 in response to concerns about our national space programs resulting from the launching of the Soviet Sputnik satellite. Over the years it has made the United States the leader in human space flight, aeronautics, space science, and space applications. NASA currently operates four Strategic Enterprises to carry out its mission. They are centered on aerospace, space science, earth science, and human exploration and development of space. While carrying out its missions over the past four decades, NASA has developed a system of laboratories that are a significant part of the nation's science and technology infrastructure. In addition to leading the exploration of space through those laboratories, NASA has made contributions to the advancement of the aircraft industry, expanded our knowledge of the universe including the planet Earth, and fostered the development of scores of commercial products.

NASA received approximately $9.6 billion in FY 1998 to support its R&D programs. Approximately $5.2 billion of this funding was for development and the remaining $4.4 billion was for research. NASA spent about $2.4 billion of the research funding at its intramural facilities, with the balance going to a variety of research performers (principally industrial firms). NASA conducts its intramural research at 11 facilities throughout the United States, including the Ames Research Center in California, which is NASA's center for research in information technology; the Goddard Space Flight Center in Maryland, which conducts a range of research relating to space flight; the Jet Propulsion Laboratory, operated by the California Institute of Technology; and the Langley Research Center in Virginia, responsible for research and development in structures and materials.[52]

From its creation, NASA has been charged by Congress with ensuring the widest possible dissemination of its R&D results. While the bulk of this work involves the sharing and transfer of technologies in the aeronautics

[52] The other Centers are the Dryden Flight Research Center (Atmospheric Flight Operations), Glenn Research Center (Turbomachinery), Independent Validation and Verification Facility (Sophisticated Software Systems), Johnson Space Center (Human Operations in Space), Kennedy Space Center (Launch and Cargo Processing Systems), Marshall Space Flight Center (Space Propulsion), Moffett Federal Airfield (Shared Federal Facility), Stennis Space Center (Propulsion Testing Systems), Wallops Flight Facility (Suborbital Research Programs), and White Sands Test Facility (Testing and Evaluating Hazardous Materials, Components, and Rocket Propulsion Systems).

and space industries, many technologies are produced that have commercial value in other sectors. To accomplish its commercial technology goals, NASA created the Commercial Technology Network, building on its 10 field centers, its nationwide network of Regional Technology Transfer Centers[53], the National Technology Transfer Center, and other organizations and publications focused on NASA technologies.

NASA uses its own legal authorities as the primary basis for its cooperative research with the private sector. Under the Space Act of 1958, NASA has broad authority to enter into "other agreements" with the private sector and others. These agreements are not regarded as procurements, grants, or cooperative agreements and are, like CRADAs, not subject to the rules governing those types of agreements. NASA has used this authority as a basis for technology transfer agreements ranging from nondisclosure agreements to funded cooperative research projects. Because of its use of the Space Act authority, NASA does not routinely use CRADAs, believing its technology transfer objectives can be achieved with greater flexibility through the use of the Space Act. NASA, however, does have the authority to enter into CRADAs and will use them in appropriate situations. NASA has an ORTA at each of its 10 research centers, including the Jet Propulsion Laboratory located at and managed by the California Institute of Technology.

The NASA Administrator, each of the Associate Administrators, the Directors of NASA's Centers, and the Manager of the NASA Management Office - Jet Propulsion Laboratory are authorized to enter into Space Act agreements. NASA's Space Act Agreement Manual is available at http://www.hq.nasa/ogc/samanual.html.

For FY 1999, NASA received 554 invention disclosures, had 85 patents issued, and received $1,226.000 from licensing of patents and copyrights.

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[53] The Regional Technology Transfer Centers include the Center for Technology Commercialization, serving the Northeast from Westborough MA; the Mid-Atlantic Technology Applications Center, serving the mid-Atlantic region from the University of Pittsburgh; the Southern Technology Applications Center, located at the University of Florida in Alachua, Florida; the Mid-Continent Technology Transfer Center, located in College Station, Texas; the Great Lakes Industrial Technology Center in Cleveland, Ohio; and the Far West Regional Technology Transfer Center at the University of Southern California in Los Angeles. NASA also supports the Research Triangle Institute in North Carolina, the MSU-NASA TechLink Center in Bozeman, Montana, and four technology incubators to assist start-up companies with commercializing NASA technologies.

The NASA General Counsel's office is responsible for all of the Agency's licensing activities. Licenses are negotiated at the Centers and are signed by the NASA General Counsel.

Department of Transportation

The Department of Transportation, the federal steward of the nation's transportation system, houses many transportation agencies and programs, all of which aim to use their R&D work to fulfill the key goals of the Department's strategic plan: improving safety, ensuring mobility, fostering economic growth, enhancing the human and natural environment, and advancing our security interests.[54]

Nine of the agencies within Transportation support transportation research, with a total FY 1998 R&D budget of $566.1 million. The Federal Highway Administration (FHWA) plays a key role in improving the quality of the nation's transportation systems, providing grants and an aggressive research program to support the state and local agencies primarily responsible for our highways. The research it sponsors explores material, structural, and information technologies designed to promote efficient and safe use of the highways. The Intelligent Transportation System (ITS) is one of its most interesting programs, working with industry, state, and local agencies and consumers to support research applying information technologies to improve highway safety, increase efficiency, and reduce energy use and adverse environmental impacts. Many other programs promote the development and transfer of innovative transportation technologies to state and local agencies.

The Federal Aviation Administration (FAA) plays a variety of regulatory roles in air transportation and carries out an extensive research and technology program to support those responsibilities. The program is carried out in cooperation with the regulated industries and other federal agencies and includes research on air traffic control systems, weather research, airport technology, aircraft safety technology, and airport security technology. The National Highway Traffic Safety Administration (NHTSA) also carries out a research program in support of its regulatory responsibilities for motor vehicle and equipment safety. This research relates to highway safety, including crashworthiness and crash avoidance as well as participation in the ITS research program.

[54] DOT Strategic Plan 1997-2002.

OFFICE OF TECHNOLOGY POLICY

The Federal Railroad Administration (FRA) promotes and enforces railroad safety, provides support to rail transportation, and supports R&D to improve rail safety and to advance high-speed rail passenger technology. Some of this research is conducted at the agency's Transportation Technology Center, operated for FRA by a railroad industry association. The Federal Transit Association (FTA) is the principal federal source of financial and technical support for public transportation. It provides grants and other funding to support transportation systems and also provides technical help to the systems through its research, development, and demonstration programs.

The U.S. Coast Guard has a wide-ranging mission that includes setting standards for commercial vessels, licensing seamen, safeguarding ports and waterways, and providing radio-navigation systems. Its research programs support all of these missions, including work on search and rescue capabilities, marine navigation, marine safety, maritime law enforcement, and integrated command, control, communications, computer, and intelligence systems. Finally, the Research and Special Programs Administration (RSPA) is responsible for intermodal transportation research, hazardous materials transportation standards, and pipeline safety. It supports multimodal research conducted at 13 University Transportation Centers and at six University Research Institutes. RSPA also leads the Department's efforts to coordinate transportation research and served as the focal point for developing the National Transportation Science and Technology Strategy—the first effort to coordinate transportation research at the federal level. RSPA also plays a key role, on behalf of the Department of Transportation in the Partnership for a New Generation of Vehicles, a cooperative research program between federal agencies and the automotive industry to triple fuel economy without compromising safety or performance.

While the bulk of the Department's research funds supports external research, three bureaus operate R&D facilities of a type that warrant participation in the CRADA and patent licensing programs. The FAA has authorized its Technical Center at Atlantic City, New Jersey, to enter into CRADAs. The FHWA has given similar authority to its laboratory in McLean, Virginia. The United States Coast Guard delegates its technology transfer work to its Research and Development Center at Groton, Connecticut. Departmental Patent Counsel coordinates patent licensing, although some agencies, like the FAA, have patent counsel at their laboratories to help with applications and paperwork. In FY 1998, the Department of Transportation entered into 13 new CRADAs, received

four invention disclosures from its researchers, and had one patent issued, but received no income from invention licensing.

Federal Laboratory Consortium for Technology Transfer

The Federal Laboratory Consortium for Technology Transfer (FLC) was established in 1974 by federal laboratory employees interested in promoting cooperation between the laboratories and the private and public sectors, including state and local governments. It was formally chartered by the Federal Technology Transfer Act of 1986 to promote and to strengthen technology transfer from the federal laboratories and was made a permanent organization by the National Technology Transfer and Advancement Act of 1995.[55]

Today the FLC consists of more than 700 research laboratories and centers from 16 federal departments and agencies. Since 1974, the FLC has brought these laboratories together with potential users of government-developed technologies. The FLC also provides a network for laboratory personnel to meet with their peers to exchange technology transfer experiences through an annual conference, electronic distribution lists, and other means.

The FLC's mission is to help federal agencies, laboratories, and their partners to accomplish the rapid integration of federal R&D resources into the mainstream U.S. economy. In order to accomplish its mission and statutory mandates, the FLC has three goals: to enhance communication, to leverage R&D investments, and to improve and innovate the technology transfer process. More specifically, the FLC has the following objectives related to each goal:

Enhance Communication

- Expand communication among member agencies and their laboratories.
- Increase dialogue with state and local governments, businesses, academia, and other external participants.
- Publicize best practices, solutions, and success stories.

[55] 15 USC § 3710(e).

Leverage R&D Investments

- Explore innovative approaches to technical assistance and other technology transfer activities.
- Reduce time, cost, and risk of R&D projects.
- Increase cost-sharing collaborations.
- Increase use of federal technology by all participants.

Improve and Innovate Technology Transfer Process

- Characterize and analyze agency technology transfer policy, procedures, and activities.
- Address barriers identified by external participants and others.
- Provide fundamental and advanced education and training to enhance the technology transfer profession.
- Provide federal agencies with an analysis of key performance measurement elements and assessment options.

To administer its affairs and services on a national level, the FLC maintains a Management Support Office that helps to coordinate the FLC's national meeting, Web site, Laboratory Locator service, exhibits, awards program, and various newsletters. All of these activities are conducted under the guidance of the national FLC Chair, Vice Chair, and Executive Board, which is composed of regional and deputy regional coordinators and committee chairs. The FLC also has a Washington, DC, Representative and a National Advisory Group.

The FLC is divided into six geographical regions: Far West, Mid-Continent, Midwest, Southeast, Mid-Atlantic, and Northeast. The regional coordinators and deputy coordinators serve as the operational link between the FLC and potential outside technology interests. These coordinators are located at member laboratories located within each region. Periodic regional meetings and regional newsletters help the member laboratories within each region develop close and effective working relationships.

FLC Strategies

- The FLC national leadership, regional coordinators, and staff are all carrying out the following strategies, which are key to implementing the FLC's overall strategic plan: Creating Innovative Partnerships. The FLC is listening to industry, interacting with trade associations on a number of levels, and responding to their specialized technological needs.

- Influencing Technology Policy. The FLC is capitalizing on its experience and expertise in technology transfer to clarify the issues effectively and influence the science and technology policy debate.

- Optimizing Diverse Resources. The FLC is coordinating its various interagency efforts to develop improved strategies and opportunities for moving government technologies to the market.

- Strengthening the FLC Structure. As the FLC provides the forum for agencies to collaborate, it is "reinventing" itself to match the new and emerging technology needs of the 21st century.

- Leading the Vision. As it heads in to the next century, the FLC is sharing information on partnering and experience with policy people to meet and anticipate the demands of changing inquiries and resources to make the most of federal technology.

- Projecting a Positive and Consistent Image. The FLC is continuing to develop strong industry-federal partnerships. It is also raising awareness of successful technology transfer between laboratories and industry. In addition to this, the FLC is further raising awareness of the breadth and depth of the FLC itself as a resource and is publicizing its mission and services.

Appendix B: The Stevenson-Wydler and Bayh-Dole Acts: A Review of the Evolution of the Technology Transfer Authorities

Technology transfer between the federal laboratories and the private sector as provided in the Stevenson-Wydler and Bayh-Dole Acts has changed significantly since 1980. The continuing congressional review of agency implementation of the legislation and the resulting amendments have provided improved technology transfer tools to the federal laboratories with which they could better carry out this important mission. Many of the changes in the law have arisen in response to problems that industry identified as impediments to effective "partnering" with the federal laboratories. The resulting amendments have been responsive to the private sector while adding value to technology transfer tools available to the federal laboratories.

Establishing the Technology Transfer Office

Before any Congressional action in this area, many individuals at federal laboratories carried out activities to support their local communities and to assist private companies. These individuals formed an *ad hoc*, inter-laboratory coordinating effort in 1974 that was later chartered by Congress as the Federal Laboratory Consortium (FLC). During 1979 and 1980, Congress sought ways to more effectively access the technologies at the federal laboratories. In the Stevenson-Wydler Act of 1980[56], the government authorized the establishment of laboratory-based offices dedicated to fostering technology transfer among the laboratories, state and local governments, and the private sector. Each federal laboratory with a total annual budget of more than $20 million was required to assign at least one full-time professional to staff an Office of Research and Technology Applications (ORTA). Beginning in fiscal year 1982, each agency was to make available at least 0.5 percent of the agency's research and development (R&D) budget to support the ORTAs at those laboratories.[57]

Establishment of the ORTAs at the federal laboratories was an important first step in formally authorizing what had been informal technology transfer activities. However, it had minimal impact at many laboratories,

[56] P.L. 96-480, 15 USC § 3701-3714.

[57] In 1986 the Act was amended to require an ORTA at any laboratory having a staff of over 200 full-time equivalent scientific, engineering, and other related positions. P.L. 99-502, amending 15 USC § 3710(b).

which assessed how much money was being spent on activities that fell within the purposes of the act, and found that they were already exceeding the 0.5 percent minimum expenditure. Through publishing papers, attending conferences, and engaging in activities to support local schools, businesses, and communities, many laboratories easily met the prescribed minimum expenditures. As a result, many regarded the Congressional mandate as fully satisfied by designating a laboratory employee to fill the mandated ORTA position, without assigning additional funds for the technology transfer mission. While the ORTA position lacked much stature within the laboratories' management structure in the early years, the ORTA was given authority to interact with state and local governments and the private sector and to strengthen such activities through inter-laboratory cooperation.

Licensing Laboratory Intellectual Property to Industry Under Statutory Authority

At the same time the Stevenson-Wydler Act was being developed to bolster laboratory technology transfer to industry, Congress was also developing what became the Uniform Federal Patent Policy Act, referred to as the Bayh-Dole Act.[58] The Bayh-Dole Act sought to improve the commercialization of federal research in two distinct ways. First, it allowed nonprofit organizations (principally universities) and small businesses to retain title to inventions arising from federally supported R&D. Second, the Act authorized federal agencies to patent their inventions and to grant licenses.

The licensing provisions applicable to universities and federal agencies are somewhat similar but the federal laboratories have somewhat more restrictions on their activities. Both must honor a statutory preference for small businesses and both retain "march-in rights" in the event a licensee does not live up to its commercialization objectives.[59] Both are required to share royalties with their inventors but only the federal agencies are required to share a specified minimum amount.[60] However, the universities do not have to give public notice of their intention to grant exclusive licenses as do the federal agencies.[61] Although both must require the domestic manufacture of products to be sold in the United States, this

[58] P.L. 96-517, 35 USC §§ 200-211.

[59] Cf. 35 USC § 202(c)(7)(D) and 35 USC § 209(c)(3) (small business preference); 35 USC § 203 and 35 USC § 209(f)(2) (march-in rights).

[60] Cf. 35 USC § 202(c)(7)(B) and 15 USC § 3710c.

[61] 35 USC § 209(d) (agency notice requirement).

requirement is applicable to all government licenses but only to exclusive licenses granted by universities.[62] In addition, the process for waiving the manufacturing requirement is more clearly stated for the universities.

In 1984, in an effort to strengthen the licensing activities of federal agencies, the Bayh-Dole Act was amended to give the Secretary of Commerce new oversight authority.[63] The Secretary was to assist federal agencies in efforts to promote the protection, licensing, and utilization of government-owned inventions. The Secretary was authorized to issue regulations governing agency licensing practices and to provide assistance and advice to the agencies in their efforts. The legislative history of the bill stated:

> The Secretary of Commerce is to develop guidelines and a number of aids to help the agencies make best use of these authorities. These aids will include techniques for evaluating the commercial potential of inventions, instruction courses for laboratory employees on the innovation process, model agreements covering the disposition of inventions for use in establishing cooperative arrangements, and advice and assistance to laboratory directors. The Secretary is to monitor the results of the program and provide annual reports to the President and the Congress.[64]

Gaining New Technology Transfer Tools Through the Use of Cooperative Research and Development Agreements

Beginning in 1984, several bills were introduced in Congress to add emphasis to the transfer of technology from the federal laboratories to the private sector. As stated in the legislative history of P.L. 98-620, "There is broad agreement that with about $17 billion going to the Federal laboratories, which employ about one-sixth of the nation's research workers, ways must be found to increase the flow of technology from those laboratories to the private sector." During Senate hearings on

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[62] Cf. 35 USC § 204 and 35 USC § 209(b).

[63] Trademark Clarification Act of 1984, P.L. 98-620, Title V, § 501, amending 35 USC § 206. This legislation also amended the procedures by reducing some of the requirements applicable to nonprofit organizations and small businesses claiming rights in inventions arising under federal funding agreements.

[64] S. Rep. No. 98-662 (October 5, 1984) reprinted in U.S. Code, Cong. & Ad. News, 5799

technology transfer legislation in 1984, several speakers argued that the federal laboratories were an untapped resource.[65]

A common theme in these legislative proposals was the need for incentives for laboratory inventors to work with industry and for a formal legal mechanism by which the federal laboratories could perform cooperative research with the private sector. On the basis of the positive experiences with university licensing and the anticipated competitive advantages to U.S. industry, Congress began to consider ways to better leverage the intellectual property generated under the significant federal R&D investments at the federal laboratories.

In 1986, the ideas were merged into a single bill that was enacted as the Technology Transfer Act of 1986. Under the new authority, government-owned, government-operated (GOGO) laboratories were empowered to cooperate with industry and other nonfederal entities and to use technology transfer tools that heretofore had not been available to all GOGO laboratories. Specific authorities granted under the act included:

- Authority for the laboratories to enter into formal contracts (called Cooperative Research and Development Agreements, or CRADAs) with nonfederal entities to cooperate in the advancement of technologies toward commercial application,
- Direction to the laboratories to identify, protect and license to the CRADA partner inventions made at the laboratory under the CRADA,
- Authority for the laboratories to establish a cash awards program to reward laboratory technical staff for inventions, innovations, and other activities that promoted commercial and mission application of technologies and domestic technology transfer,

[65] Governor Dick Thornburg of Pennsylvania said: "There are over 380 federal laboratories in the United States. The eight in Pennsylvania are performing research in areas ranging from coal and forestry to food quality. We should be certain that we are taking maximum advantage of their resources and results to stimulate economic growth in this country. Although these laboratories perform a significant amount of the research taking place in our country today, they have not always been as aggressive as they might be in transferring their technology from the laboratory to the private sector." S. Rep. No. 98-662 (Oct. 5, 1984)

- Authority for the laboratories to retain income from licensing of laboratory intellectual property to reward inventors and other technical staff members who made technology transfer contributions and to fund mission-related education and training, intellectual property management costs, or mission-related scientific R&D, and

- Authority for agencies to waive their rights in inventions and assign title to CRADA partners.

In addition, the Act provided important guidance to the laboratories about the role that technology transfer should play in each laboratory's culture:

- Technology transfer, consistent with mission responsibilities, was to become a responsibility of each laboratory science and engineering professional.

- Each laboratory director was to ensure that efforts to transfer technology were considered positively in laboratory job descriptions, employee promotion policies, and evaluation of the job performance of scientists and engineers in the laboratory.

- Individuals filling positions in an ORTA were to be included in the overall laboratory/agency management development program to ensure that highly competent technical managers were full participants in the technology transfer process.

- To enhance the effectiveness of laboratory-based technology transfer programs, each ORTA was to prepare application assessments for selected R&D projects in which that laboratory was engaged and which in the opinion of the laboratory might have potential commercial applications.

- Each laboratory was encouraged to participate, where feasible, in regional, state, and local programs designed to facilitate or stimulate the transfer of technology to benefit the region, state, or local jurisdiction in which the federal laboratory is located.

In 1988 Congress amended the Stevenson-Wydler Act to expand the scope of intellectual property that could be licensed under a CRADA. The amended law permitted laboratories "to negotiate license agreements ... for inventions and other intellectual property developed at the labora-

tory." [66] Congress explained the change as intended "to allow parties negotiating a cooperative agreement to permit contractual considerations of all intellectual property arising under the agreement."

Reinforcing Federal Technology Transfer Initiatives: Executive Order 12591

In 1987, President Reagan issued Executive Order 12591 to encourage federal agencies and their laboratories to move knowledge from the research laboratories into the development of new products and processes by fully implementing the statutory authorities granted by the Bayh-Dole Act, Federal Technology Transfer Act, and related legislation.

The Order directed the agencies, to the extent permitted by law and within funding allocations, to extend rights to all contractors, regardless of size, to elect to retain title to all inventions made under federally funded R&D. In addition, the Order recognized the international implications of these activities and set guidelines to ensure the protection and preservation of U.S. interests in CRADAs or patent licenses involving foreign entities. These guidelines require that agencies, "in consultation with the United States Trade Representative, give appropriate consideration" to a series of factors relating to the foreign country whose entities are involved in the transaction. These factors include the ability of U.S. companies to participate in cooperative research and licensing in the country, the country's intellectual property protection policies, and the adequacy of its export control measures.

Granting CRADA Authority to Department of Energy Laboratories and Other Amendments

The National Competitiveness Technology Transfer Act of 1989[67] gave all government-owned, contractor-operated (GOCO) laboratories authority to enter into CRADAs under the Federal Technology Transfer Act. Most of the GOCO laboratories were part of the Department of Energy (DOE) laboratory system and this law effectively empowered all federal laboratories to participate in federal technology transfer activities. The Act provided a number of special provisions applicable to the GOCO CRADA process.

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[66] P.L. 100-519, amending 15 USC § 3710a(a).

[67] P.L. 101-189, amending 15 USC §§ 3710a and 3710b.

The Act also increased reporting requirements relating to intellectual property management. The federal agencies were required to submit to Congress, with their annual budget request, an explanation of the agency's technology transfer program for the preceding year and the agency's plans for conducting its technology transfer function for the upcoming year. Plans for an upcoming year were to include provisions for securing intellectual property rights in laboratory innovations with commercial promise and plans for managing such innovations to benefit U.S. industrial competitiveness.

Other significant changes in the 1989 Act related to the treatment of proprietary information generated in connection with a CRADA. Congress believed that the threat of disclosure under the Freedom of Information Act of confidential information had been a significant impediment to corporate participation in CRADAs. For that reason, the Act included language authorizing the laboratories to withhold from disclosure certain types of information either supplied by the private sector partner or generated in the course of the CRADA activities. Congress authorized the laboratories to protect from disclosure (including disclosure under the Freedom of Information Act) "information that results from research and development activities" under the act for a period of up to 5 years from its development. This CRADA information must be of a type "that would be a trade secret or commercial or financial information that is privileged or confidential if the information had been obtained from a non-Federal party" participating in a CRADA.[68]

Establishing Minimum Expectations for Licensing of CRADA Inventions

In 1995, legislation was introduced to provide statutory guidance to both the laboratories and their private sector partners in licensing rights in intellectual property generated under a CRADA. The National Technology Transfer and Advancement Act of 1995[69] ensures that a private sector CRADA partner will have sufficient rights in laboratory inventions made under the CRADA to obtain whatever competitive advantage may result from commercializing the resulting technology. The law requires the collaborating party be offered, at a minimum, "the option to choose an exclusive license for a pre-negotiated field of use " for any laboratory

[68] 15 USC § 3710a(c)(7)(B).

[69] P.L. 104-113, amending portions of 15 USC §§3710-3710d.

invention under the agreement.[70] In return, the laboratory is to receive a license to practice the invention on behalf of the government and may also, in certain defined circumstances, require the collaborator to license others on reasonable terms.[71]

Recent Legislative Proposals

A bill to amend the Stevenson-Wydler Act was introduced in the 106th Congress and passed by the House of Representatives.[72] The bill is expected to be considered by the Senate in the next session of Congress. The bill was intended to streamline agency licensing practices, especially in the case of exclusive licenses, and to make other improvements to the laboratories' ability to license their technologies. The bill would simplify the notice requirements applicable to the granting of an exclusive or partially exclusive license, requiring a minimum notice period of fifteen days. It would also confirm the authority of the laboratories to grant licenses to pre-existing intellectual property under a CRADA, subject to the procedural requirements of the agency patent licensing authorities of the Bayh-Dole Act. Other provisions of the bill would enable the federal laboratories to work more effectively with universities and small businesses in bundling related pieces of intellectual property for licensing.

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[70] 15 USC § 3710a(b)

[71] The government may exercise such rights "only in exceptional circumstances" and only if it determines that the collaborator has failed to meet commitments intended to ensure economic benefit to the United States or that certain other defined conditions are met. 15 USC § 3710a(b)(1)(B) and (C).

[72] H.R. 209, 106th Cong., 1st Sess.

Appendix C: An Update on Historical Performance Measurements

During the past decade, the Department of Commerce gathered data elements, which have served primarily to indicate *how much* technology transfer *activity* had occurred. In our previous reports, the point was made that most of these data can be referred to as input data relating to the technology transfer process, as opposed to *outputs* or *outcomes* from technology transfer projects that serve the stated purposes of both the Stevenson-Wydler and Bayh-Dole Acts. In addition to the data collected by Commerce, the Office of Management and Budget and most laboratories and agencies have gathered supplemental technology transfer information, which they use for their own assessments.

Historically, the data elements gathered for the report to Congress and the President accounted for the following items:

- Number of inventions disclosed.
- Number of patent applications filed.
- Number of invention licenses granted by federal laboratories.
- Income from licenses by federal laboratories and agencies.
- Number of active CRADAs.

This year Commerce requested several other data elements on an optional basis and two that were required from all agencies. Those required elements are:

- Number of patents issued.
- Number of new CRADAs initiated.

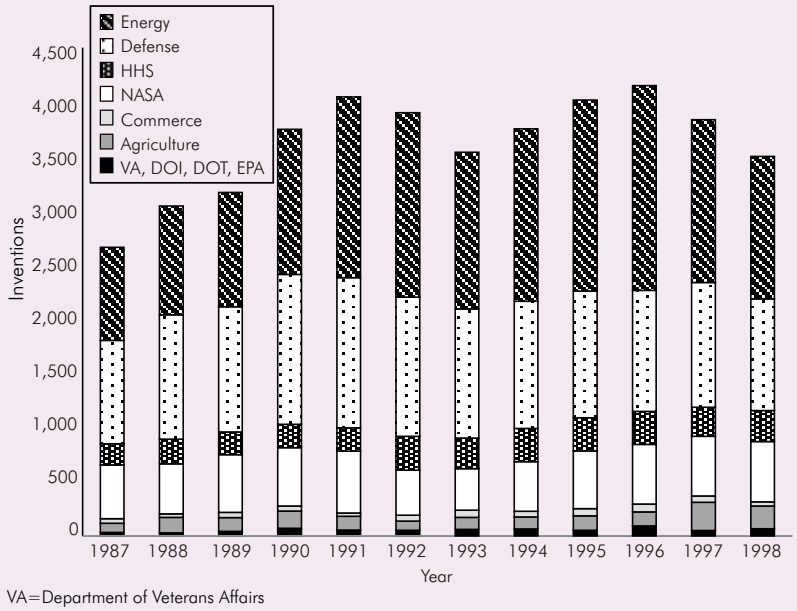
Of these seven data elements reported by all agencies, four could arguably be considered outputs: the number of inventions disclosed, the number of licenses granted, the income from licensing, and the number of CRADAs initiated. The other three, although important metrics, relate primarily to the input side of the ledger.

The additional data elements requested from the agencies and the laboratories were intended to provide more insight into the outputs from the

technology transfer activities engaged in by the federal laboratories with industry. A few of those additional data elements will be considered in the following discussion as it relates to the data being reported.

From Figure 1, "Number of Federal Laboratory Inventions Disclosed,"* there does not appear to have been a marked increase in the total number of inventions disclosed since 1987, the time of the inclusion of technology transfer as part of agency missions. Of course, the existence of these new responsibilities and new agreements would not necessarily alter the rate at which new discoveries occur.

Figure 1. Number of Federal Laboratory Inventions Disclosed



VA=Department of Veterans Affairs

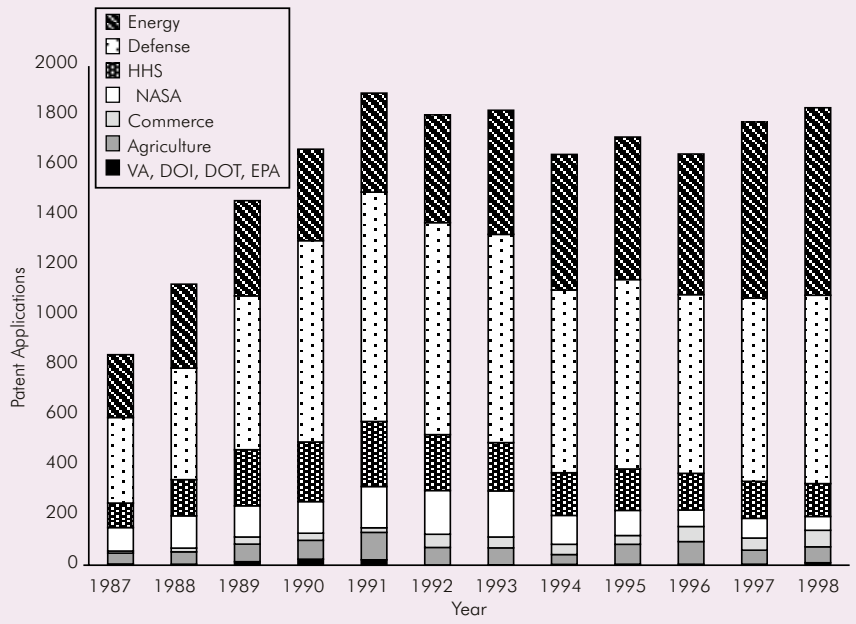
The number of inventions disclosed changed somewhat at the Department of Energy (DOE). During the last half of the 1980s, DOE gave its government-owned, contractor-operated (GOCO) laboratories the authority to elect title to inventions, which minimized the agency's direct involvement in the patenting of inventions and shifted much of the responsibility for invention review and patenting to their laboratories. Thus, as DOE's laboratories assumed responsibility for intellectual property

*Accompanying tables are presented at the end of this appendix.

management, the number of DOE disclosures fell below historic levels for a few years, but are now rising to earlier levels.

Figure 2, "Number of Patent Applications on Federal Laboratory Inventions," suggests that, as the government-owned, government-operated laboratories expanded their involvement with industry under CRADAs, more attention was paid to the commercial potential of inventions and the laboratories became more active in their patenting activities. Similarly, as DOE's GOCO laboratories received their CRADA authority and began to partner with industry, their patenting activities nearly tripled. Following

Figure 2. Number of Patent Applications on Federal Laboratory Inventions

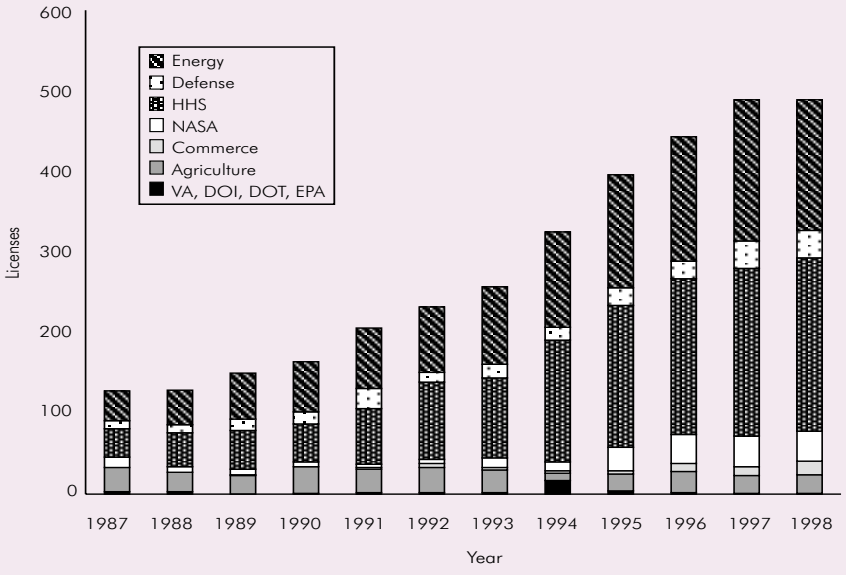


those early increases in activity, the number of applications has reached a relatively constant rate. The data presented in Figure 3, "Number of Patents Issued on Federal Laboratory Inventions," indicate that Defense and Energy laboratories file applications on a greater percentage of their disclosures than most other agencies, and thus account for nearly 75 percent of all patents issued to federal agencies. It is likely that this relates more to their tradition of "defensive patenting" than to the quality of disclosures at the agencies.

Figure 3. Number of Patents Issued on Federal Laboratory Inventions

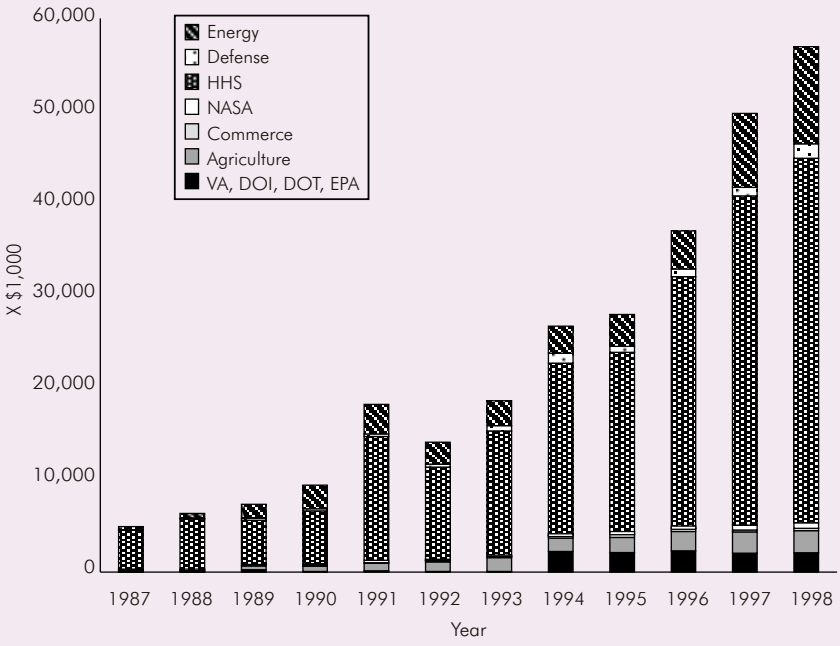
Figure 4, "Number of Licenses Granted for Federal Laboratory Inventions," indicates that licensing is becoming part of the culture for at least a few of the federal laboratories and that the laboratories are beginning to

Figure 4. Number of Licenses Granted for Federal Laboratory Inventions



get results from their patent portfolios. Figure 5, "Income from Licenses for Federal Laboratory Intellectual Property," shows a steady increase that reflects the results of proactive licensing efforts by a few laboratories. Comparison with similar income data reported by the Association of University Technology Managers (AUTM) suggests that an annual growth rate of about 20 percent may be within normal expectations for this phase of program development for licensing of federally funded inventions. This is especially true considering that the agencies and their laboratories have more restricted licensing opportunities (copyright is unavailable to the laboratories) and must comply with more public interest criteria in licensing their technologies than universities. As with universities, a few laboratories and agencies have had early successes and currently dominate the statistics. However, many laboratories are beginning to invest more in the commercial assessment of their intellectual property portfolios and are training their staffs to become capable licensing professionals. As a result, the number of licenses and the earned income from royalties will probably continue to grow at a modest rate.

Figure 5. Income from Licenses for Federal Laboratory Intellectual Property inThousands of Dollars



Additional data collected from agencies accounting for the bulk of the licensing income show that about 65 percent of the royalties received were for earned income from the sales or use of licensed inventions. This tracks with the experience at universities, as reported by the AUTM

survey, and is a more meaningful metric than total licensing income. Accounting for earned royalties as opposed to license issue fees or minimum annual royalties is the best measure of commercial application of licensed federal inventions.

Figure 6. Number of Active CRADA Projects at Federal Laboratories

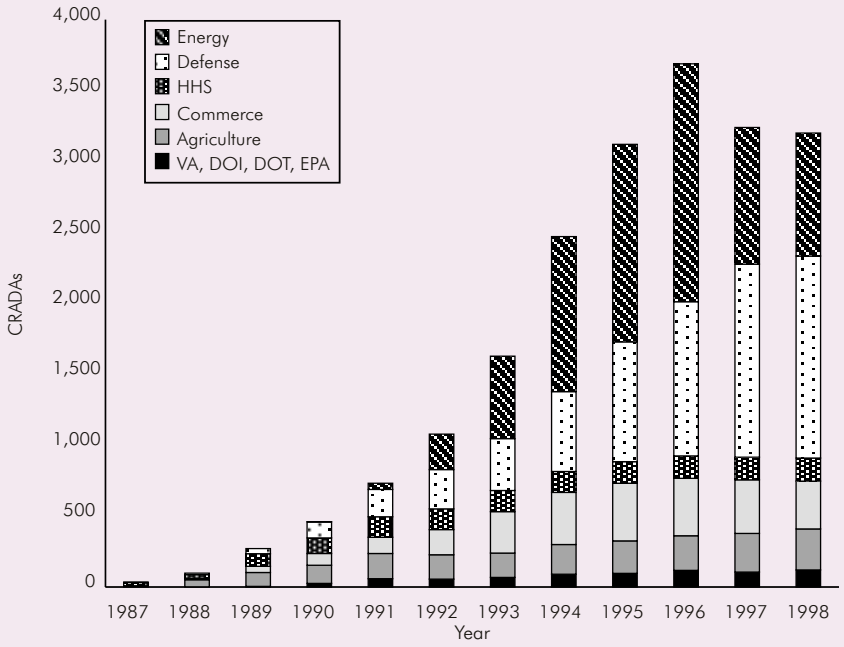
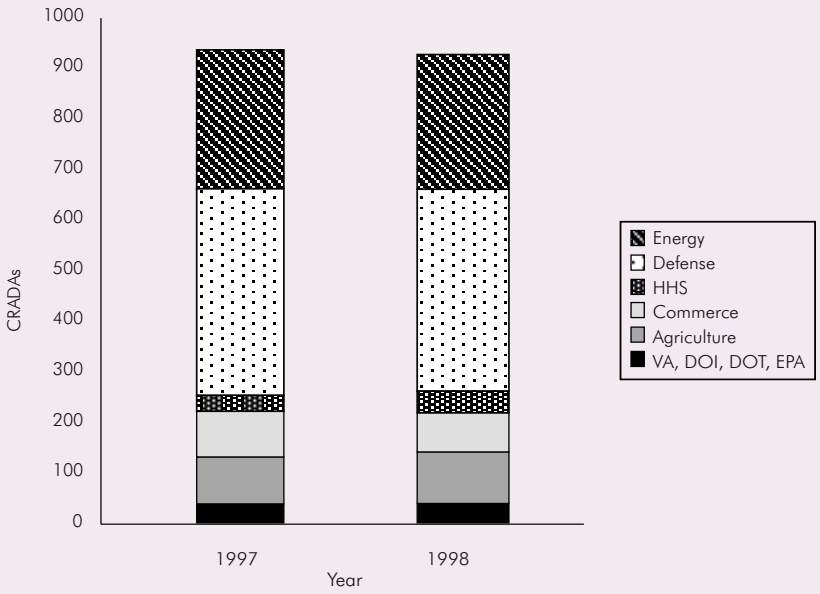


Figure 6, "Number of Active CRADA Projects at Federal Laboratories," shows that the Department of Defense and DOE laboratories have attracted the greatest number of industry partners. This is to be expected because of the historical relationships that their laboratories have had with the defense industries and because of the substantial numbers of scientists and engineers at their laboratories.

The marked decline of CRADAs at the DOE laboratories at the end of 1996 reflects a decision in 1994 by DOE to end its Technology Transfer Initiative and to phase it out over a 2-year period beginning in 1996. The Initiative, which provided funding for laboratory involvement in CRADAs at both DOE's Energy and Defense laboratories, was closely linked to competencies at each individual laboratory. It had been managed at the laboratory levels until 1993 when management of the initiative was centralized at headquarters. When the decision was made to

Figure 7. Number of CRADA Projects Initiated at Federal Laboratories



phase out the Initiative, the number of CRADAs with industry declined by 50 percent. Congress continues to fund the Defense Programs' Initiative at about 20 percent of its peak funding and project prioritization and selection have been returned to the laboratories.

Figure 7, "Number of CRADA Projects Initiated at Federal Laboratories," shows that the number of new CRADAs remains practically constant, even when considered on an agency-by-agency basis. In some cases, the laboratories may be at the saturation point, having absorbed as much collateral work with the private sector as the level of appropriated funding will support. However, as data are collected in subsequent years, there may be variations among agencies as a result of programmatic shifts by agencies and their laboratories.

OFFICE OF TECHNOLOGY POLICY

TABLE 1. Number of Federal Laboratory Inventions Disclosed

Agency	FY 1987	FY 1988	FY 1989	FY 1990	FY 1991	FY 1992	FY 1993	FY 1994	FY 1995	FY 1996	FY 1997	FY 1998
Agriculture	83	144	127	158	127	83	110	111	133	129	260	208
Commerce	43	31	49	46	30	55	66	51	65	71	58	40
Defense	953	1147	1153	1383	1383	1283	1189	1172	1168	1115	1150	1028
Air Force	83	90	169	160	102	160	140	140	200	190	138	121
Army	248	348	276	376	463	438	413	388	363	338	312	264
Navy	622	709	708	847	959	685	636	644	605	587	700	643
Energy	857	1003	1053	1335	1666	1698	1443	1588	1758	1886	1500	1313
EPA	0	0	0	12	20	9	22	19	15	20	9	14
HHS	194	226	209	215	215	311	282	307	307	305	268	287
Interior	3	6	3	26	26	1	2	2	2	2	5	5
NASA	496	462	532	538	570	416	384	457	532	550	550	554
Transport	0	0	0	1	2	1	1	1	0	4	2	4
VA	33	28	42	58	33	44	39	45	36	71	40	50
Total	**2662**	**3047**	**3168**	**3772**	**4213**	**3901**	**3538**	**3753**	**4016**	**4153**	**3842**	**3503**

TABLE 2. Number of Patent Applications on Federal Laboratory Inventions

Agency	FY 1987	FY 1988	FY 1989	FY 1990	FY 1991	FY 1992	FY 1993	FY 1994	FY 1995	FY 1996	FY 1997	FY 1998
Agriculture	44	50	71	76	110	70	68	40	80	91	56	64
Commerce	8	15	28	28	18	53	43	41	35	60	49	66
Defense	343	447	616	807	919	850	835	732	759	716	735	755
Air Force	49	47	122	145	178	155	161	122	148	108	100	116
Army	177	203	216	236	274	260	246	232	218	204	192	219
Navy	117	197	278	426	467	435	428	378	393	404	443	420
Energy	252	336	382	366	397	432	497	543	571	564	705	751
EPA	4	5	5	6	8	12	15	15	24	18	13	11
HHS	98	145	225	239	261	224	193	171	166	147	148	132
Interior	5	4	11	15	21	1	2	2	2	2	2	5
NASA	94	129	125	127	165	175	185	116	101	66	79	55
Transport	0	0	0	1	1	0	0	1	2	2	1	3
VA	NA	NA	3	8	NA	0	0	0	0	0	1	2
Total	**848**	**1131**	**1466**	**1673**	**1900**	**1817**	**1838**	**1661**	**1740**	**1666**	**1789**	**1844**

TABLE 3. Number of Patents Issued on Federal Laboratory Inventions

	FY1997	FY1998
Agriculture	45	75
Commerce	23	19
Defense	554	579
Air Force	88	89
Army	169	168
Navy	297	322
Energy	384	512
EPA	12	1
HHS	152	171
Interior	1	3
NASA	72	85
Transport	0	1
VA		
Total	**1243**	**1446**

TABLE 4. Number of Licenses Granted for Federal Laboratory Inventions

Agency	FY 1987	FY 1988	FY 1989	FY 1990	FY 1991	FY 1992	FY 1993	FY 1994	FY 1995	FY 1996	FY 1997	FY 1998
Agriculture	30	24	23	33	29	31	28	9	21	26	22	23
Commerce	0	0	1	0	2	5	3	3	4	10	11	17
Defense	10	10	14	15	25	12	17	16	22	22	34	34
Air Force	1	2	2	4	1	1	3	3	4	6	7	5
Army	3	6	2	3	9	7	3	12	12	19	14	13
Navy	6	2	10	8	15	11	14	13	18	16	13	16
Energy**	37	43	57	62	75	81	96	118	140	154	175	162
EPA	0	0	0	1	2	2	2	9	1	2	1	0
HHS	35	42	48	47	69	96	99	151	176	193	208	215
Interior	3	3	0	0	0			8	3		0	0
NASA	13	7	7	6	4	5	12	11	29	36	51	58
Transportation	0	0	0	0	0						0	1
VA	0	0	0	0	0							
Total	**128**	**129**	**150**	**164**	**206**	**239**	**260**	**337**	**408**	**462**	**502**	**510**

**Does not include licenses for copyrighted works.

TABLE 5. Income from Licenses for Federal Laboratory Intellectual Property in Thousands of Dollars

Agency	FY 1987	FY 1988	FY 1989	FY 1990	FY 1991	FY 1992	FY 1993	FY 1994	FY 1995	FY 1996	FY 1997	FY 1998
Agriculture	133	120	420	559	836	1044	1483	1450	1635	2091	**2300**	**2400**
Commerce	34	81	62	52	26	0	0	0	0	0.27	**196**	**241**
Defense	44	49	211	239	286	331	567	1081	646	836	**924**	**1560**
Air Force	27	31	27	44	43	47	90	59	102	142	**190**	**212**
Army	10	5	41	58	113	78	77	110	100	335	**256**	**430**
Navy	7	13	143	137	130	206	400	912	444	359	**478**	**918**
Energy	346	545	1499	2560	3193	2369	2703	2915	3455	4122	**8009**	**10536**
EPA	0	0	0	3	74	60	75	230	110	300	**60**	**100**
HHS	4245	5434	4804	5839	13384	10133	13584	18654	19727	27277	**35692**	**39500**
Interior	46	38	61	41	58	0	0	2000	2000	2000	**2000**	**2000**
NASA	73	79	84	113	292	133	158	311	349	343	**1,053**	**1,226**
Trans/VA	0	0	163	7	14						**0**	**0**
Others	4	2	33	16	0							
Total	**4925**	**6348**	**7337**	**9429**	**18163**	**14070**	**18570**	**26641**	**27922**	**36969**	**50234**	**57563**

TABLE 6. Number of Active CRADA Projects at Federal Laboratories

Agency	FY 1987	FY 1988	FY 1989	FY 1990	FY 1991	FY 1992	FY 1993	FY 1994	FY 1995	FY 1996	FY 1997	FY 1998
Agriculture	9	51	98	128	177	172	172	208	229	244	273	288
Commerce	0	9	44	82	115	177	292	368	407	406	377	337
Defense	3	10	36	113	193	277	365	563	845	1086	1360	1424
Air Force	0	2	7	13	26	6	25	32	66	223	251	246
Army	3	8	27	80	115	212	260	389	549	531	740	817
Navy	0	0	2	20	52	59	80	142	230	332	369	361
Energy	0	0	0	1	43	250	582	1094	1392	1677	963	868
EPA	0	0	2	11	31	30	28	35	30	35	34	37
HHS*	22	28	89	110	144	146	149	147	152	158	161	163
Interior	0	0	1	12	11	1	3	9	15	22	23	30
Transport	0	0	0	1	9	17	30	38	37	43	36	39
VA	0	0	1	2	8	8	7	9	14	17	12	15
Total	**34**	**98**	**271**	**460**	**731**	**1078**	**1628**	**2471**	**3121**	**3688**	**3239**	**3201**

*In 1996 NIH began using CRADAs to transfer research samples into its laboratories.

The numbers presented here do not include "Material CRADAs."

TABLE 7. Number of CRADA Projects Initiated at Federal Laboratories

	FY1997	FY1998
Agriculture	93	102
Commerce	90	77
Defense	408	399
Air Force	72	55
Army	189	210
Navy	147	134
Energy	274	266
EPA	11	12
HHS*	32	43
Interior	9	7
Transport	14	13
VA	6	9
Total	**937**	**928**

*In 1996 NIH began using CRADAs to transfer research samples into its laboratories.

The numbers presented here do not include "Material CRADAs."

Appendix D: Seeking Industry's Perspective on Federal Technology Transfer

To prepare this report, OTP solicited the views of industry regarding federal technology transfer issues. This was accomplished by identifying companies that had partnered with industry under a number of different types of technology transfer agreements. As an initial activity, agencies and their laboratories were asked to submit the names of private sector firms who had participated with laboratories under CRADAs.

The purpose for engaging the outside CRADA participants was to:

- Gain insight on how much impact the CRADAs have had on their businesses and/or in advancing their technologies.
- Identify issues that have made partnering with the federal laboratories difficult.
- Seek to understand how close the coupling was between the laboratory and the outside participant.
- Identify "best practices" among the various agencies and recognize ways that the outside participants believe the processes and practices could be improved.

In gathering the information from industry, the National Science Foundation contracted with SRI International on behalf of the Department of Commerce to provide expert assistance in developing interview regimes and to conduct telephone conversations with private sector firms and to facilitate a roundtable discussion with industry.

The telephone conversations were conducted using a collection of questions helped to carry out a meaningful dialogue. The conversations were not a survey, but were intended to gain a sense of the diversity of industry/laboratory interactions and lessons learned. The following list of topical questions was used by the consultants in carrying out the telephone conversations:

1. "Your company/university has engaged in ___ CRADA(s) with a federal lab(s). Why did you decide to pursue a cooperative project(s) with the lab(s)?"

2. "How did you identify the lab(s) with which you wished to engage in a cooperative agreement(s)?"

3. "When the scope of work was developed, was the work plan one that you felt would be mutually beneficial, or was it focused more on the interests of your company or the laboratory?"

4. "What were your expectations at the beginning of the project?"

5. "When the project was completed, had your expectations been met? If not, please explain."

6. "Did either your company or the laboratory identify and protect intellectual property (IP) during the course of the project? (If the laboratory did, ask "Did you formally license the IP from the laboratory?")"

7. "In negotiating the terms of the CRADA, did you find any specific provisions as impediments to doing business with the laboratory? How were those matters resolved?"

8. "When the CRADA was completed, did you remain in contact with your laboratory technical staff member?"

9. "If you have had CRADAs with more than one laboratory/agency, did you notice differences in the manner in which negotiations or the actual project were conducted? If differences, what were they and what was their effect?"

10. "Did the technology you received contribute directly or indirectly to your company's success? If yes, how?

11. "Are there things that could be done to improve the technical or business interactions between your company and the laboratory(s)?"

12. "Would you enter into another CRADA with that laboratory, or any laboratory? If not, why not?"

13. "Would you encourage others to enter into CRADAs?"

The companies contacted were:

Arcturus Engineering
CMS Defense Systems
CryoGen, Inc.
General Atomics
Goodyear
Motorola Corporation
PG&E
Procter & Gamble
Smith-Kline Beecham
Spawr Industries
Superconductivity Components, Inc.
Vical, Inc.

When the telephone discussions with these companies were completed, a series of issues was identified which would serve as topics for a "roundtable discussion" with companies that had engaged in significant industry/laboratory cooperative research. The External Research Directors' Network (ERDN) of the Industrial Research Institute agreed to participate in such a roundtable discussion at its planned meeting on April 19, 1999. The title of the session was "The Industry Perspective, Partnering with Federal Laboratories Through CRADAs." In attendance were 30 individuals representing 25 different companies.

The two consultants from SRI facilitated the meeting. A panel of ERDN representatives from six major companies served as a forum to stimulate broader discussions by the larger group. The questions used to focus the meeting were the following:

- How did you decide with which lab(s) to work?
- What were your expectations going in?
- Were your expectations met?
- How close were the technical interactions?

- Were there formal and/or regular communications between the parties during the project?
- How did this benefit your company?
- Do you think the technology transfer benefited the laboratory?
- Were there problems that you encountered either in doing the agreement or in conducting the work?
- If the work is complete, has there been any follow-on collaboration such as licensing?
- What did you learn from the experience?
- Is partnering with federal laboratories of continuing value to your company? Why?

The results of the panel discussion and the telephone conversations were the basis of much of the information contained in Section 3 of this report.

The companies represented at the ERDN roundtable were:

Air Products And Chemicals, Inc.
Alcoa Inc.
Akzo Nobel Chemicals
Armstrong World Industries, Inc.
The Dexter Corporation
The Dow Chemical Company
DuPont
Eastman Chemical Company
Eastman Kodak Company
Eaton Corporation
Ford Motor Company
General Electric Company
The Gillette Company
Hewlett-Packard Company
ICI Americas/Glidden
Industrial Research Institute, Inc.
Intel Corporation
Kellogg Company
Kraft Foods, Inc.
Lockheed Martin Corporation

Nalco Chemical Company
The Procter & Gamble Company
Rohm And Haas Company
The Sherwin-Williams Company
UOP, Inc.